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BASELINE HUMAN HEALTH RISK ASSESSMENT FOR THE CALIFORNIA GULCH SUPERFUND SITE

PART C

EVALUATION OF WORKER SCENARIO

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Prepared for:

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Foreword

This document is a portion of one of three parts of the baseline human health risk assessment at the California Gulch Superfund Site. Although this part (Part C) was prepared first (prior to the completion of Parts A and B), the text makes reference to the planned contents of Parts A and B so that Part C may be combined with these sections without further editing after they are completed.

This assessment has been performed following extensive consultation with EPA Headquarters offices, regional offices, and the Agency's Technical Review Workgroup for Lead. This assessment represents Region VIII's best estimate of risk based on exposure parameters specific to the California Gulch site. Use of these parameters at other sites without careful consideration of site-specific information is discouraged.

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1.0 INTRODUCTION

1.1 SITE DESCRIPTION AND HISTORY

The California Gulch Superfund Site is located in and around the community of Leadville, Colorado, about 100 miles southwest of Denver. Leadville was the site of extensive mining, milling and smelting operations beginning about 1860. Most of the operations had ceased by about 1900, although several facilities continued operations into the 1920s (Western Zinc) and the 1960s (AV Smelter) (Walsh 1993). Nearly all of the mines within the site boundaries are presently inactive and all of the mills and smelters have been demolished. Part A of this report presents a more detailed history of the mining and refining operations in Leadville, along with detailed site maps.

The site was placed on the National Priorities List (NPL) in 1983 ~~mainly~~ because of concern over the impact of mine drainage on surface waters in the California Gulch and the Arkansas River. Subsequent site investigations revealed the presence ~~of a number of~~ heavy metals in soils in and around the current residential and commercial areas of Leadville, and a preliminary risk assessment (WESTON 1991) indicated that contaminant levels were high enough to be of potential human health concern. Lead and arsenic were identified as being the primary chemicals of potential human health concern.

1.2 FINAL HUMAN HEALTH RISK ASSESSMENT

Since the time the site was placed on the NPL, the U.S. Environmental Protection Agency (EPA) and a number of Potentially Responsible Parties (PRPs) have performed a variety of studies to define the nature and extent of contamination at the site and to help evaluate the level of risk which site contaminants pose to humans. Based on these data, the EPA is preparing a Final Baseline Human Health Risk Assessment for the site. This comprehensive risk assessment will consist of three main parts, as follows:

- Part A is to evaluate the risks which lead in the environment poses to current and future residents of the community

- Part B is to evaluate the risks which metals other than lead pose to current and future residents of the community

- Part C is to evaluate the risks which environmental contamination poses to current or future workers in the commercial and business district of the community, and to people who engage in recreational activities (hunting, hiking, bike riding, picnicking, etc.) in areas in and around the community.

This document is one portion of Part C of the risk assessment. covering populations exposed to environmental contaminants in the workplace.

1.3 APPROACH TO PART C OF THE RISK ASSESSMENT

In response to concerns raised by Leadville officials and business leaders over potential liabilities associated with development of businesses within the Superfund site, EPA committed to performing an "expedited" risk evaluation to determine, as quickly as possible, if environmental contamination was of concern at any locations presently zoned for commercial and industrial purposes, and if so, to define where remedial actions were and were not needed. Similarly, in order to address potential concerns regarding the development of a proposed bike path around the community, EPA committed to performing an expedited evaluation of potential risks associated with recreational land use.

In order to perform these risk assessments on an accelerated schedule, EPA incorporated the following assumptions and approaches into the standard risk assessment procedures:

1. The assessments focus only on lead and arsenic. Even though other metals occur at elevated concentrations in the environment around Leadville (e.g., see WESTON 1991), experience at other sites, as well as the results of preliminary calculations at this site, indicate that lead and arsenic are the "risk drivers". Thus, focusing on these two chemicals is not likely to underestimate risk.

2. The assessments focus only on exposure to soil and dust, and only by the ingestion pathway. Exposure to other media (e.g., waste piles, sediments, surface water, etc.) and exposure to soil/dust via other pathways (e.g., dermal, inhalation of particulates) are considered to be of minor concern for workers.

3. Rather than calculating risk at all specific properties and locations where commercial land use is possible, calculations were performed for both lead and arsenic to identify concentrations ("action levels") in soil which were of potential concern, and these concentrations were compared to findings of remedial investigations of soil concentration values in order to identify locations where these values might be exceeded.

The specific methods used for calculating action levels for lead and arsenic in soil are detailed below, along with the results of the evaluations for commercial land use scenarios.

2.0 LEAD EVALUATION

2.1 OVERVIEW

The health risks which lead poses to a specified population can often be investigated in two different ways:

- Direct measurement of blood lead values in members of the population of concern
- Measurement of lead in environmental media, and calculation of the range of risks those levels of lead could pose to individuals or populations

As discussed below, each of these approaches has some advantages and some limitations, and the best assessment of lead risks incorporates the results of both types of approaches.

Blood Lead Monitoring

One way to investigate the human health risks from lead in the environment is to measure the concentration of lead in the blood (PbB) in randomly-selected members of the population of concern. The health risks associated with these measured PbB values can be evaluated by comparison to current guidelines for acceptable values. Blood lead studies that also include reliable environmental and demographics data can provide valuable insights into the media and exposure pathways that are the primary sources of concern in a population.

However, there are some limitations to the use of blood lead measurements as the only index of lead risk. First, care must be taken to ensure that a sufficient number of people are studied, and that these people are a representative sub-set of the population of concern. Second, blood lead values in an individual may vary as a function of time, so a single measurement may not be representative of the long-term average value in that individual. Third, it is expected that blood lead values will differ between individuals, even when they are exposed under the same environmental conditions. Thus, an acceptable blood level measured in one individual (e.g., a worker at a commercial establishment) does not necessarily mean that some other individual (e.g., some other worker who might be exposed at the same location in the future) might not have a higher (and possibly unacceptable) blood lead level. Fourth, population-based studies are not well-suited to detecting the occurrence of occasional sub-locations where risk is elevated, even if average risks are acceptable. Finally, blood lead measurements reflect exposures and risks under current site conditions, which may not always be representative of past or future site conditions. For these reasons, results from blood lead studies may not provide a complete description of the range of risks which might exist in a population.

Predictive Approach

Because of the limitations in the direct measurement approach, it is valuable to employ a predictive as well as an empirical method for evaluation of lead risk. These models can then be used to assess the risks from lead under conditions which cannot be measured (e.g., risks to hypothetical future people in an area where there are no current exposures), to identify which exposure pathways are likely to be contributing the largest risk to a population, and to evaluate the likely efficacy of various remedial alternatives.

A number of predictive lead exposure models exist. For example, the EPA has developed an integrated exposure, uptake and biokinetic (IEUBK) model to assess the risks of environmental exposure in residential children. In addition, models have also been developed by Bowers et.al (1994), O'Flaherty (1993), Legget (1993) and the State of California (CEPA 1992) to assess the effects of lead exposure in older children and adults. In general, these models require (as site-specific input) information on the levels of lead in various environmental media, and on the amount of these media contacted by the population of concern. From this input, the models calculate the expected levels of blood lead in the exposed population.

However, all predictive models are subject to a number of limitations. First, there is inherent difficulty in providing the model with reliable estimates of human exposure to lead-contaminated media. For example, exposure to soil and dust is difficult to quantify because since human intake of these media are likely to be highly variable, and it is very difficult to derive accurate measurements of actual intake rates. Second, it is often difficult to obtain reliable estimates of key pharmacokinetic parameters in humans (e.g., absorption fraction, distribution and clearance rates), since direct experiments in humans is not acceptable. Finally, the absorption, distribution and clearance of lead in the human body is an extremely complicated process, and any mathematical model intended to simulate the actual processes is likely to be an over-simplification. Thus, model calculations and predictions are usually rather uncertain.

Weight-of-Evidence Evaluation

As the discussions above make clear, there are advantages and limitations to both the direct blood measurement approach and the UBK modeling approach. Therefore, the most appropriate means for evaluating risks from lead is to consider the results of both analyses, taking into account the uncertainties and limitations of each. Final conclusions regarding current and future risk should thus be based on a balanced assessment of information from all sources.

2.2 POPULATION OF PRINCIPLE CONCERN

Usually, lead risk assessments focus on young children, since young children tend to have higher lead exposures than older children or adults, because young children tend to absorb more lead than do adults, and because young children are more susceptible to the adverse effects of lead on the nervous system. Part A of this risk assessment provides a more thorough description of the adverse effects of lead in children, and presents an evaluation of the risks which lead may pose to children who live in Leadville.

This part of the risk assessment focuses on lead risks to workers (assumed to be adults). Within this population, the subpopulation most likely to be of concern are pregnant women. This is because pregnant women may tend to absorb more lead than non-pregnant women or men, and because the fetus of the pregnant women is likely to be especially susceptible to the adverse effects of lead. Therefore, pregnant women and women of child-bearing age are selected as the sub-population of principle concern.

2.3 TARGET BLOOD LEAD LEVELS IN PREGNANT WOMEN

The EPA has not yet issued formal guidance on the blood lead level that is considered appropriate for protecting the health of pregnant women or other adults. However, EPA recommends that there should be no more than a 5% likelihood that a young child should have a PbB value greater than 10 ug/dL (EPA 1991b). Since the exposed worker and recreational populations at this site are assumed to include pregnant women, and because the fetus is exposed to lead levels nearly equal to thos of the moth r, the health criterion selected for use in this evaluation is that there should be no more than a 5% chance that the fetus of a pregnant woman would have a PbB above 10 ug/dL. This health goal is equivalent to specifying that the 95th percentile of the PbB distribution in fetuses does not exceed 10 ug/dL:

$$PbB_{95}\text{fetal} \leq 10 \text{ ug/dL}$$

The relationship between fetal and maternal blood lead concentration has been investigated in a number of studies. Goyer (1990) reviewed a number of these studies, and concluded that there was no significant placental/fetal barrier for lead, with fetal blood lead values being equal to or just slightly less than maternal blood lead values. The mean ratio of fetal PbB to maternal PbB in three recent studies cited by Goyer was 0.90. Based on this, the 95th percentile PbB in the mother is then:

$$PbB_{95}\text{maternal} = 10/0.90 = 11.1 \text{ ug/dL.}$$

That is, there should be no more than a 5% chance that a pregnant women will have a blood lead value above 11.1 ug/dL.

It is important to note that the choice of 10 ug/dL as the upper 95th percentile limit for the fetus does not imply that exposures above this definitely cause unacceptable health effects and that levels below this are definitely without risk. Rather, there is a graded increase in the severity of adverse effects as blood lead levels increase. Typically, frank clinical effects are not observed in children at blood lead levels less than 60-80 ug/dL, and effects that occur at blood levels of about 10 ug/dL are subtle and are generally observable only in well-designed population studies. Therefore, there are differences in opinion between health professionals as to what blood lead level should be treated as the acceptable limit. The choice of a health limit of 10 ug/dL by EPA is based on a consensus among agency scientists that effects which begin to appear at this exposure level are sufficiently undesirable to warrant avoidance (EPA 1991b).

2.4 MEASURED BLOOD LEAD VALUES IN WOMEN IN LEADVILLE

Data on blood lead levels in 173 adults in Leadville were collected in 1991 by Dr. Robert Bornschein of the University of Cincinnati. Within this group were 127 women of child-bearing age (assumed to be age 16 to 45 years), 29 of whom were pregnant and 23 of whom were nursing at the time of the survey. A summary of the blood lead values observed in these women is presented below.

Parameter	All Women Age 16-45	Not pregnant or nursing	Pregnant Women	Nursing Women
Number of people	127	75	29	23
Measured PbB Values				
Mean	2.7 ug/dL	2.8 ug/dL	2.3 ug/dL	3.1 ug/dL
Standard deviation	1.3 ug/dL	1.3 ug/dL	1.3 ug/dL	1.0 ug/dL
Geometric mean (GM)	2.4 ug/dL	2.5 ug/dL	1.9 ug/dL	2.9 ug/dL
Geom.Std.Dev.(GSD)	1.8	1.7	2.1	1.5
Maximum	7.1 ug/dL	6.8 ug/dL	7.1 ug/dL	5.3 ug/dL
Calculated 95th Percentile PbB	6.3 ug/dL	6.1 ug/dL	6.4 ug/dL	5.4 ug/dL

Comparison of these data with the health goal described above in Section 2.3 (95th percentile PbB = 11 ug/dL) indicate that, at the population level, current women residents of Leadville, including pregnant and nursing women, are unlikely to be exposed to sufficient levels of lead to be of concern.

Despite the indication that current exposures are below a level of concern, there are limitations to these data and the results should be interpreted with some caution. First, there were a relatively small number of women surveyed, so confidence in the population statistics (GM, GSD, 95th percentile) is only moderate. For example, the 95% confidence interval for the mean blood lead in pregnant women is approximately 1.5 to 3.3 ug/dL. Second, information is not available on which (if any) of these women were exposed in the workplace, so it is difficult to utilize these observations to draw direct conclusions regarding the acceptability of exposures in the workplace. Third, as noted above (see Section 2.1), blood lead data of this sort only indicate exposures under current conditions, and may not reveal risks which could arise in the future.

2.5 PREDICTED BLOOD LEAD LEVELS IN PREGNANT WOMEN

There are several mathematical models which have been proposed for evaluating lead exposure in adults, including those developed by Bowers et al. (1994), O'Flaherty ([illegible]), Legget (1993), and the State of California (CEPA 1992). Of these, the model of Bowers et al. is most nearly consistent with the approach employed by the EPA in the IEUBK model for children, and is also very simple to apply. For these reasons, this method was used (with some modifications) for calculating the concentration of lead in soil which would be of potential concern to adults engaged in recreational activities at this site.

2.5.1 Basic Equation

The Bowers model predicts the blood lead level in an adult exposed to lead in a specified occupational setting by summing the "baseline" blood lead level (PbB_0) (that which would occur in the absence of any occupational exposures) with the increment in blood lead that is expected as a result of occupational exposure to soil or dust. The latter is estimated by multiplying the absorbed dose of lead from occupational soil/dust exposures by a "biokinetic slope factor" (BKSF). Thus, the basic equation is:

$$PbB = PbB_0 + BKSF*[C_s*IR_s*EF_s*AF_s + C_d*IR_d*EF_d*AF_d] \quad (1)$$

where:

PbB = Blood lead level (ug/dL) in a population of adults exposed to lead-contaminated soil or dust via occupational activities

PbB_0 = "Baseline" blood lead level in adults not exposed to lead-contaminated soil via occupational activities, but including other background exposures, including residential exposure

BKSF = Biokinetic slope factor (ug/dL increase in blood lead per ug/day lead absorbed)

C = Arithmetic mean concentration (ug/g) of lead in soil (C_s) or dust (C_d), averaged over the workplace location where exposure occurs

IR = Mean daily intake rate of soil (IR_s) or dust (IR_d) during occupational activities in areas of contamination (g/day)

EF = Exposure frequency (days/yr) to soil (EF_s) or dust (EF_d) during occupational in areas of contamination

AF = Absolute absorption fraction (bioavailability) of lead in soil (AF_s) or dust (AF_d).

2.5.2 Input Parameters

Most of the parameters in this model are not constants, but vary from person to person or from place to place. Thus, to use this model to predict the distribution of blood lead values that would be observed in a population of women in the workplace, it is necessary to describe the range and relative likelihood of values for each parameter. This is done in the form of Probability Distribution Functions (PDFs). Once PDFs are defined for each parameter, commercially available software systems can be used to combine the inputs and predict the distribution of likely blood lead values in women workers. The text below discusses what is known about each parameter, and the PDF selected to represent each.

Background Blood Lead Level (PbB_0)

As discussed above, it is assumed the subpopulation of workers of greatest potential concern for risks from lead are women of child-bearing age. Two sources of data are available that could be useful in characterizing PbB_0 for this subpopulation. First are the site-specific data collected during the study performed in Leadville by the University of Cincinnati in 1991 (Bornschein 1994). As noted above, this study collected data from 126 women between the ages of 16 and 45, including a sub-set of 29 pregnant women. The GM values for these two groups were 2.4 ug/dL and 1.9 ug/dL, respectively, with GSD values of 1.8 and 2.1, respectively.

A second source of information on baseline blood lead levels is available from the NHANES III study (Brody et al. 1994). The geometric mean PbB values (ug/dL) reported for women aged 20-49 was 1.7 for whites, 2.0 for Hispanics, and 2.2 for blacks, each with GSD values close to 2.0. Because Leadville is primarily a mixture of whites and Hispanics, these data suggest that a GM value of about 1.9 might be expected for women in Leadville. Comparison of this value with those from the Bornschein study suggests that women in Leadville have blood lead values that are similar to national averages, although the value of 2.4 ug/dL for women age 16-45 is consistent with the view that levels in Leadville women might be about 0.4-0.6 ug/dL higher than the national average. (If so, this difference is not large enough to be of toxicological significance in the average case).

Based on the combined site-specific data on blood lead distributions in pregnant women and women age 16-45, and supported by the data from the national survey, the PDF selected to model the value of PbB_0 is as follows:

$$PbB_0 = \text{LOGNORMAL}(1.8,2.0)$$

BKSF

The biokinetic slope factor proposed by Bowers et al. is 0.375 ug/dL per ug/day absorbed. This value is estimated from an observed slope of 0.06 ug/dL increase in blood lead of adult men per ug/L of lead in first draw water. Calculation of the BKSF from the Pocock data requires a number of assumptions regarding how much total water was ingested, how much of this was first draw and how much was drawn after the pipes were flushed, the decrease in lead concentration when the pipes were flushed, and the amount of lead absorbed from the ingested water. Appendix A presents an analysis of the range of possible BKSF values which might be derived from the Pocock study, depending on the input assumptions. Based on this analysis, EPA believes the Pocock study data are consistent with a BKSF of about [illegible] ug/dL per ug/day absorbed. A similar value of 0.444 can be derived from the data of Rabinowitz et al. (1974), although this study is based on only two male individuals, so the resulting value may not be highly representative. Calculations performed using the pharmacokinetic model developed by O'Flaherty (1993) show that BKSF is not a constant, but depends on age, sex, and lead body burden. Estimated values range from 0.25 to 0.53 for a 25 to 35 year-old woman, assuming an absorption fraction of 0.08 (Gradient 1995). Based on this information, the PDF selected to model the value of BKSF is as follows:

BKSF = UNIFORM(0.25,0.50)

It should be noted that this range of BKSF values is still based mainly on data from adult males. However, data from the NHANES III survey reveal that the blood level of men tends to be higher than for women (Brody et al. 1994). This suggests that either men tend to have higher exposures to lead, or that the BKSF for women is lower than for men. It is not known which of these is true, but if the exposures are thought to be similar, then use of a BKSF based on adult males may tend to be conservative when applied to women.

C_s and C_d

Data are available from a number of studies on the distribution of lead values in soils in the community of Leadville. These data reveal that average lead concentrations vary as a function of location within the community, tending to be highest in the eastern sections of town where most of the historic mining-related activities occurred. However, for the purposes of simulating the expected distribution of blood lead values in current women residents, the most appropriate data are for the community as a whole. Statistics available from several major studies are summarized below.

Study	Sample Type	N	Mean	STD
Walsh 1988	Depth = 0-6"	354	1890	3220
WESTON 1991	Depth = 0-6"	3489	2320	2260
Bornschein 1994	Perimeter Bare Area	202 174	1520 1510	2450 2290
CDM 1994	Depth = 0-6"	2762	1900	3200

In all of these studies, the data are observed to be left-skewed in an approximately lognormal distribution. Based on these studies, the variability in C_s was estimated with the following PDF:

C_s = LOGNORMAL(2000,2500)

Only one study (Bornschein 1994) has investigated the distribution of lead levels in 243 interior dust samples in Leadville. These data were collected in private residences, but it seems reasonable to assume that levels in commercial establishments are likely to be similar. The observed mean and standard deviation of the dust values were 850 ppm and 700 ppm, respectively. As was the case for soils, the data are observed to be left-skewed in an approximately lognormal distribution. Based on this, the value of C_d was modeled as:

C_d = LOGNORMAL(850,700)

IR_s and IR_d

The parameters IR_s and IR_d are the average daily intake of soil and dust during occupational exposures. Such intake is believed to occur mainly as a result of soil or dust adherence to the hands, followed by hand-to-mouth contact. It is expected that the amount of soil and dust ingested by workers is highly variable, depending on parameters such as:

- The type of business, and whether or not workers at the business frequently come into direct contact with soil. EPA refers to such businesses as "contact-intensive", while occupations such as office worker, teacher, storekeeper, etc., are considered "non-contact intensive".

- The amount of soil or dust available for adherence to the hand. For indoor exposures, this is probably related to the dust "loading" on surfaces which come into contact with the hands. For outdoor exposure, it is probably related to the amount of soil that is available for direct contact (i.e., not covered with pavement or vegetation).

- The tendency of soil or dust to adhere to the hand. This, in turn, probably depends on the particle size and moisture content of the soil or dust, and possibly the amount of moisture on the hand as well

- The frequency of hand-to mouth contact by workers following contact with contaminated dust or soil

Based on information provided by the Leadville Chamber of Commerce, most businesses in Leadville fall into the "non-contact intensive" category. This includes 65 retail stores, 21 office buildings, 22 restaurants, 13 motels/hotels, and 46 service-type businesses. Of the relatively few "outdoor businesses" (lumberyard, gas stations, yard maintenance service, etc), many have paved parking or working areas, and are not likely to involve extensive and repeated contact with soil.

There are relatively few studies on the amount of soil and dust ingestion by adults, and there are no direct measurements of soil/dust ingestion during non-contact intensive occupational activities. Thus, there is very high uncertainty associated with selection of these parameters. To address this uncertainty, the EPA (1993) has issued draft guidance on recommended default soil and dust intake by non-contact intensive workers, as follows:

Central tendency = 50 mg/day
Reasonable maximum = 100 mg/day

These recommendations are adopted for use in this assessment, and are expressed as a PDF as follows:

$$IR_{s,d} = \text{TRIANGULAR}(10,30,120)$$

This PDF has a mean of approximately 50 mg/day and a 95th percentile of approximately 100 mg/day, consistent with EPA recommendations.

EF_s and EF_d

There are no site-specific data on the number of days each year a worker is at work, but draft EPA guidance (EPA 1993) recommends an assumed central tendency exposure frequency at the workplace of 219 days per year and an RME value of 250 days per year. Assuming a lower bound of 200 days/yr, the total number of days at work is modeled as:

$$EF_{total} = TRIANGULAR(200,219,250)$$

As noted above, most businesses in Leadville are not soil-contact intensive, so most exposure is expected to be associated with dust ingestion while indoors at the workplace. However, some workers may spend some days, or parts of some days outside. There are no data on the amount of time spent outdoors by workers in Leadville, but because there are over 150 days/year when the ground is either frozen or snow-covered, it is expected that the maximum number of work days when soil exposure could occur is probably not higher than 100 days/yr, with an average value of approximately 10 days/yr. Based on these concepts, the indoor (dust) and outdoor (soil) exposure frequencies for workers are modeled with the following PDFs:

$$EF_s = TRIANGULAR(0,10,100)$$
$$EF_d = EF_{total} - EF_s$$

AF_s and AF_d

"Baseline" Absorption Fraction. A number of studies have been published on the absorption of lead by adults. In a study with 5 adult male volunteers, Rabinowitz et al. (1980) found that the absorption fraction depended on whether the lead was ingested along with food or was ingested 9 hours after the last meal. For lead ingested along with food (or for lead ingested in the diet), the absorption fraction was 8-10%. For lead ingested by 9-hr fasted subjects, the absorption fraction was 30-37%. (No food was ingested by these subjects until hour 16). O'Flaherty (1993) reviewed several reports (including Rabinowitz et al. 1980) and concluded that gastrointestinal absorption of lead in adults ingesting mixed diets is 4-11%, with a mean probably about 8-9%.

Clearly the choice of the most appropriate absorption fraction depends on what is assumed regarding the time of lead ingestion in relation to the time of last eating. For workers, it seems reasonable to assume that most will arrive at work shortly after having breakfast, and will also ingest food at lunch time. Likewise, it seems reasonable to expect that most recreational visitors will have eaten within several hours of visiting the site. Thus, EPA considers a value of 10% likely to be representative the absorption fraction in most people, but individuals who do not eat breakfast or lunch, or who otherwise are exposed a number of hours after the last meal, might have an absorption fraction as high as 30%. Based on this, the PDF selected to model the baseline absorption fraction (AF_0) in workers is as follows:

$$AF_0 = TRIANGULAR(0.04,0.10,0.30)$$

Effect of Pregnancy. Several studies have established that calcium absorption increases about two-fold in women during pregnancy (e.g., Heaney and Skillman 1971). Because at least some lead absorption from the gastrointestinal tract probably occurs via calcium transport systems, it is quite plausible that during pregnancy the absorption of lead also increases, and there are scattered observations from recent studies which provide partial support for this conclusion (Rothenberg et al. 1994, Manton and Angle 1995, Franklin et al. 1995). However, both the site-specific data and data from other studies (e.g., Alexander and Delves, 1981) show that blood lead values do not increase two-fold during pregnancy, and may even decrease. This supports the view that the absorption fraction for lead does not increase (at least not as much as for calcium), or that other changes in distribution and clearance kinetics occur. Based on this information, it is assumed that the absorption fraction during pregnancy is about 1.5-times that in non-pregnant women:

$$AF_0(pregnancy) = 1.5*AF_0$$

As noted above, because observed blood lead values do not usually increase by this large a factor during pregnancy, inclusion of this adjustment without a compensatory adjustment in the BKSF term is more likely to overestimate than underestimate blood lead values during pregnancy.

Adjustment for Bioavailability in Mine Wastes. There are several studies which provide evidence that lead in soil and mine wastes may be absorbed less-extensively than lead in food or water. This includes a study performed by the EPA in which absorption of lead from a composite soil sample from Leadville was measured in immature swine. Based on preliminary analyses of the data from this study (EPA 1995), it appears that lead in the Leadville soil was absorbed about 60-80% as much as was a known soluble form of lead (lead acetate). Thus, it is reasonable to expect that the amount of lead absorbed from ingested soil would be about 60-80% of the "default" value for lead absorption by pregnant women. In order to be consistent with the current assumption regarding absorption of lead from soil that is used in the IEUBK model (EPA 1994a), a relative bioavailability of 60% was assumed for these calculations. Data are not available on how RBA might vary from location to location across the site, but speciation studies indicate that there are differences in the relative abundance of different forms of lead in different locations. In the absence of data, it is assumed that RBA could vary from about 30% to 80%, and is modeled as follows:

$$RBA = TRIANGULAR(0.3,0.6,0.8)$$

The net absorption fraction for lead in soil or dust is given by:

$$AF_{s,d}(pregnancy) = AF_0(pregnancy)*RBA$$

Summary of Inputs

Table 1 lists the PDFs selected to model the variability in each of the inputs needed to estimate blood lead levels in the population of pregnant women who work in Leadville.

2.5.3 Results

Monte Carlo simulations were performed (5000 iterations per simulation) using the PDFs above to describe the variability in blood lead values predicted in women in Leadville as a result of workplace exposure to environmental lead. The results are summarized below.

Parameter	Calculated Values for Pregnant Workers	Measured Values	
		Women (16-45)	Pregnant Women
Geometric Mean	3.3	2.4	1.9
Average	3.9	2.9	2.3
95th Percentile	8.7	6.3	6.4
GSD	1.8	1.8	2.1

As shown, the predicted population-based blood lead distribution for pregnant workers in Leadville is within the health-based goal described in Section 2.1 (95th percentile < 11 ug/dL), supporting the conclusion that current environmental exposure levels in Leadville are not likely to be of concern to pregnant women.

Comparison of the calculated values with the values reported by Bornschein reveal that the calculated values are higher than the measured values. This observation is consistent with two interpretations (which are not mutually exclusive):

- The women who participated in the study were not exposed in the workplace
- One or more of the PDFs selected for use in the simulations tend to overestimate current exposure levels in the workplace

2.6 CALCULATION OF WORKPLACE SOIL ACTION LEVELS FOR LEAD

2.6.1 Overview

Even though both the measured and the predicted blood lead distributions in the population of women in Leadville indicate that the risks of unacceptable exposure to lead are low, it is still

TABLE 1. SUMMARY OF VARIABILITY DISTRIBUTION FUNCTIONS FOR ESTIMATION OF LEAD EXPOSURE IN WORKERS

Model Input	Abbr.	Units	Distribution Shape	Parameters of Distribution
Baseline blood lead	PbB_0	ug/dL	Lognormal	GM = 1.8 GSD = 2.0
Biokinetic slope factor	BKSF	ug/dL per ug/d	Uniform	Min = 0.25 Max = 0.50
Concentration in soil	C_s	mg/kg	Lognormal	Mean = 2000 STD = 2500
Concentration in dust	C_d	mg/kg	Lognormal	Mean = 850 STD = 700
Ingestion rate of soil and dust at workplace	IR_{sd}	mg/day	Triangular	Min = 10 Mode = 30 Max = 120
Exposure frequency at work	EF_{total}	days/yr	Triangular	Min = 200 Mode = 219 Max = 250
Exposure frequency outdoors	EF_s	days/yr	Triangular	Min = 0 Mode = 10 Max = 100
Exposure frequency indoors	EF_d	days/yr	Calculated as EF_{total} - EF_s	--
Absorption fraction from food and water during pregnancy	AF_{preg}	--	Triangular	Min = 0.06 Mode = 0.15 Max = 0.45
Relative bioavailability of lead in soil	RBA	--	Triangular	Min = 0.3 Mode = 0.6 Max = 0.8

possible that there are sub-locations within the community where the concentrations of lead are sufficiently high to pose a risk to individuals exposed at those locations, now or in the future. If such locations exist, they might not have been detected by either the measurement of blood lead or the calculation of predicted values if a) no women are currently exposed at those areas, b) women are exposed, but the areas are relatively small compared to community as a whole, or c) if, by chance, no women with higher than average intakes of soil or dust were exposed in these areas.

One way to estimate the maximum soil concentration at some specified workplace or recreational area that is not of concern to pregnant workers or recreational visitors is to find the soil concentration that gives a 95th percentile PbB value of 11 ug/dL. The steps needed to achieve this solution are discussed below.

2.6.2 Basic Equation

Recall that the basic equation used to predict blood lead in an exposed individual is:

$$PbB = PbB_0 + BKSF*[C_s*IR_s*EF_s*AF_s + C_d*IR_d*EF_d*AF_d] \quad (1)$$

Because this equation contains terms for both soil and dust exposure, it cannot be solved for the soil term (C_s) unless the dust term (C_d) is defined as a dependent variable whose value can be predicted from the value of soil. Assuming that soil comprises some (but not all) of the mass of indoor dust, the concentration of lead in dust can be described using an equation of the following form:

$$C_d = D_0 + Ksd*C_s$$

where:

D_0 = Concentration of lead in dust that is not due to contamination from soil at the workplace

Ksd = Mass fraction of dust that comes from outdoor soil at the workplace

Substituting this expression into the basic equation above and solving for the value of C_s which corresponds to some specified target blood lead value yields:

$$C_s = (a - c*D_0)/(b + c*Ksd)$$

where:

$$a = (PbB_{target} - PbB_0)/BKSF$$
$$b = IR_s*EF_s*AF_s$$
$$c = IR_d*EF_d*AF_d$$

2.6.3 Uncertainty PDFs

The desired value for each of the input parameters above is the true mean. If these true means were known, then the equation would yield a single numeric value (the action level) that is equal to the soil lead concentration corresponding to a 5% chance that any woman exposed at that workplace would have a blood lead value above 11 ug/dL. However, there is substantial uncertainty in the true mean for most of these variables. Therefore, each input parameter was described by a PDF which describes uncertainty about the true mean, and these PDFs were used in a Monte Carlo simulation to estimate the plausible range of the true action level. It is important to distinguish this analysis of <u>uncertainty</u> around the true action level from the analysis of <u>variability</u> in community blood lead levels presented above in Section 2.5.

<u>Target Blood Lead Level</u>

As discussed earlier, EPA has chosen 11.1 ug/dL as the upper 95th percentile of the acceptable blood lead distribution in exposed women. This value can be used to estimate the geometric mean of the blood lead distribution if the GSD is known, using the following equation::

$$PbB_{GM}target = 11.1/GSD_i^{1.645} \qquad (3)$$

The GSD_i in this equation is intended to describe the individual variability between different people in the amount of environmental media which they ingest, in the fraction of the lead which they absorb from those media, and in the increment which that absorbed lead causes on their average PbB value. Normally, values of GSD_i are estimated from observed distributions of PbB values in a population. The observed GSD from the population is referred to as GSD_p. At this site, the measured GSD_p value in women age 18-40 was 1.7 (N = 66), and in pregnant women was 2.1 (N = 29).

The relationship between GSD_p and GSD_i is usually difficult to resolve. Conceptually, a GSD_p value reflects variability of two main types: 1) variability in individual activity patterns and toxicokinetic factors, and 2) variability in the concentrations of lead in environmental media. The first component is equal to GSD_i. Thus, empirical GSD_ps represent an upper bound on the value of GSD_i.

EPA has described a general method for estimating GSD_i from a data set by stratifying the population into groups with similar environmental exposure levels (EPA 1994a). This stratification tends to reduce the contribution due to environmental variation, and the value of GSD_p will tend to approach GSD_i. The results of this approach using the site-specific data for women of child-bearing age at this site yields the following results:

Area	N	GSD
A	8	2.0
B	7	1.5
C	21	1.8
D	12	1.5
E	3	1.5
F	2	1.4
G	4	1.4
H	2	1.2

Interpreting these sub-population GSD_p values as GSD_i values is complicated because exposures in sub-areas may not really be uniform (this is of special likelihood in Leadville), and because the value tends to become statistically unstable as the number of people in the subpopulation becomes small. Nevertheless, the analysis by subareas generally supports the conclusion that the GSD_i is probably lower than the population-based value of 1.7. Based on these considerations, the PDF selected to describe the range of possible true mean values for GSD_i is:

GSD_i = TRIANGULAR(1.4,1.6,1.8)

<u>Baseline Blood Lead (PbB_0)</u>

As discussed above, site specific data identify a geometric blood lead value of 2.5 for women of child-bearing age and 1.8 for pregnant women in Leadville (Bornschein 1994). Comparison of these values with the national mean of about 2.0 for women age 20-40 suggests that women in Leadville may have blood lead values that are perhaps about 0.5-0.6 ug/dL higher than the national average. If so, this is most likely due to the higher-than-average exposure to lead in the home or in the general community. To the extent that the measured GM blood lead value does include contributions from the environment that will be addressed as part of the residential risk assessment, it is not appropriate to include this contribution in the derivation of the PRG for recreational areas. In essence, this would require these areas to meet a more stringent goal to account for the exposures occurring in other areas. Based on these considerations, the PDF selected to describe the range of plausible values for the true GM PbB_0 is:

PbB_0 = TRIANGULAR(1.7,2.0,2.5)

<u>Soil/Dust Relationship (D_0 and Ksd)</u>

The normal EPA default assumption is that the concentration of contaminants in indoor dust are equal to those in outdoor soil (EPA 1989, 1994a). However, this assumption has proved to be overly conservative at most mining sites. At Leadville, the University of Cincinnati obtained paired measurements of lead concentrations in soil and dust at about 200 locations (Bornschein 1994). Based on simple mass-fraction considerations, the contribution of soil to dust can be described by an equation of the form:

$$C_d = D_0 + K_{sd}*C_s$$

where:

D_0 = Concentration of lead in dust due to sources other than yard soil
K_{sd} = Mass fraction of yard soil in indoor dust

Finding the best-fit values for these two parameters (D_0, K_{sd}) is complicated by the effect of measurement error, which tends to obscure any relationships which do exist. As discussed in Part A of this risk assessment, one approach that is fairly insensitive to the effects of measurement error is to estimate D_0 as the mean dust concentration in locations where the concentration in outdoor soil is low (e.g., less than 300 ppm), and to estimate K_{sd} as:

$$K_{sd} = \frac{\left(\bar{D} - D_o\right)}{\bar{S}}$$

where:

$\bar{D}$ = Average concentration of lead in dust
$\bar{S}$ = Average concentration of lead in soil

Based on this analysis, the estimated values are:

D_0 = 500 ppm
K_{sd} = 0.26

Because D_0 reflects the contribution of sources outside the boundaries of a property to contamination of dust at that property, EPA does not consider it appropriate to include this term when calculating an action level. In essence, this would penalize a property and require a more stringent clean-up than if adjacent areas were not contaminated. Therefore, for the purposes of this calculation, D_0 is set to zero. Because of the relatively high uncertainty in the calculated value for K_{sd}, this parameter was described with the following PDF:

K_{sd} = TRIANGULAR(0.2,0.25,0.6)

<u>Other Parameters</u>

All of the other parameters needed to calculate the nominal action level for lead in workplace soil are the true means from the variability distributions discussed in Section 2.5 above. Professional judgement was used to select PDFs that describe the range of plausible values for the trues means, as summarized in Table 2.

TABLE 2. SUMMARY OF UNCERTAINTY DISTRIBUTION FUNCTIONS FOR ESTIMATION OF LEAD SOIL ACTION LEVEL

Model Input	Abbr.	Units	Distribution Shape	Parameters of Distribution
Individual geometric standard deviation	GSD_i	--	Triangular	Min = 1.4 Mode = 1.6 Max = 1.8
Baseline blood lead	PbB_0	ug/dL	Triangular	Min = 1.7 Mode = 2.0 Max = 2.5
Biokinetic slope factor	BKSF	ug/dL per ug/d	Uniform	Min = 0.3 Max = 0.5
Ingestion rate of soil and dust	IR_{sd}	mg/day	Uniform	Min = 10 Max = 90
Exposure frequency at work	EF_{total}	days/yr	Uniform	Min = 210 Max = 230
Exposure frequency outdoors	EF_s	days/yr	Triangular	Min = 5 Mode = 10 Max = 20
Exposure frequency indoors	EF_d	days/yr	Calculated as EF_{total} - EF_s	--
Absorption fraction from food and water during pregnancy	AF_{preg}	--	Triangular	Min = 0.1 Mode = 0.15 Max = 0.4
Relative bioavailability of lead in soil	RBA	--	Uniform	Min = 0.4 Max = 0.8
Mass fraction of yard soil in dust	K_{sd}	--	Triangular	Min = 0.2 Mode = 0.25 Max = 0.6

2.6.4 Results

The results of a Monte Carlo simulation of the uncertainty around the action level are shown in Figure 1. As seen, the plausible range of action levels could conceivably range from as low as 2,200 ppm (the 5th percentile) to as high as 19,100 ppm (the 95th percentile). Central tendency values include 6,100 ppm (the geometric mean) and 7,700 ppm (the arithmetic mean).

2.6.5 Comparison of Action Levels with Measured Concentrations

Numerous studies have been performed to collect data on lead levels in soil in and around Leadville. Figure 2 is a map taken from CDM (1994), which shows lead levels in surficial soils (0-1 inch) in and around Leadville. These results are similar to those described in WESTON (1994) (e.g., see Figure 5-4 in that report), which shows lead levels in the 0-6 inch layer of soil in and around Leadville. Inspection of these maps reveals that average lead levels are mostly below the central-tendency range of plausible action levels (6100-7700 ppm) for most areas zoned for commercial land use, except possibly for some areas located in the historic mining area east of town and in the vicinity of the former AV Smelter located southwest of town.

Note that it is average lead levels over an area which should be compared to the soil action level. That is, occasional measurements or small "hot-spots" of concentrations above the action level do not necessarily constitute evidence that an area is unsafe.

2.6.6 Sensitivity Analysis

Appendix B presents a sensitivity analysis of the Bowers model as it is used to calculate an action level for lead. In brief, the most important parameters, judged in terms of how much the calculated value may vary as a function of the range of plausible input values, are the target blood lead level, the soil/dust ingestion rate, the absorption fraction from food and water, and the mass fraction of soil in indoor dust. The sensitivity to these parameters is due mainly to the large uncertainty (credible range) around these parameters.

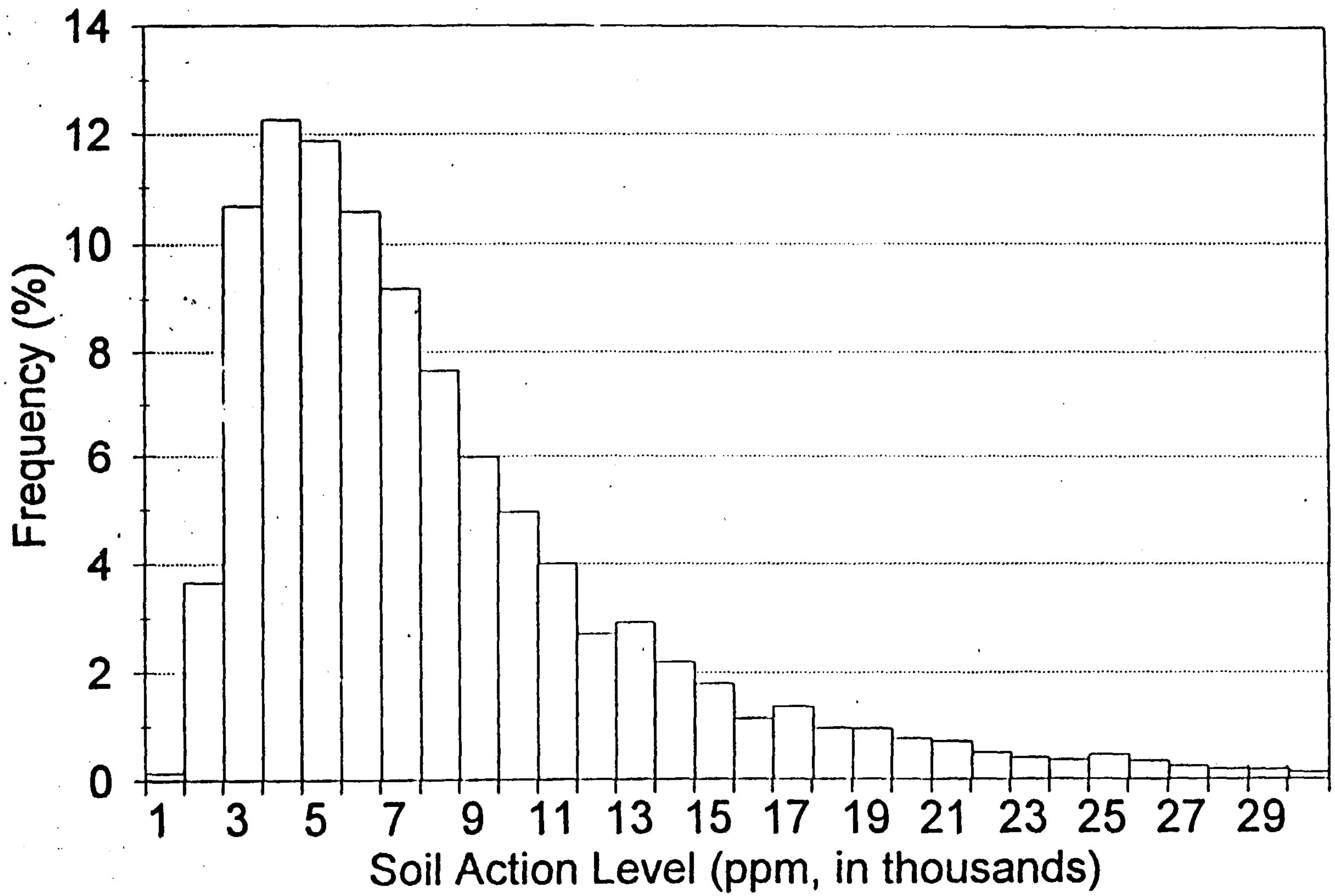
2.7 WEIGHT-OF-EVIDENCE EVALUATION

Three types of information are available to evaluate the risks to women of exposure to environmental lead contamination in the workplace.

1) Direct Blood Lead Measurements in Women

Direct blood lead measurements of women in Leadville indicate that, under current conditions, there is a low probability that of a woman will have a blood lead level higher than the goal set by EPA. Based on the expectation that a number of these women do work, this observation supports the view that current workplace exposures to lead are not of concern. However, direct measurement techniques might not detect the occurrence of a few specific locations where risks are high, and these data may not reflect risks which could occur in the future.

Figure 1 Uncertainty in Soil Action Level for Lead



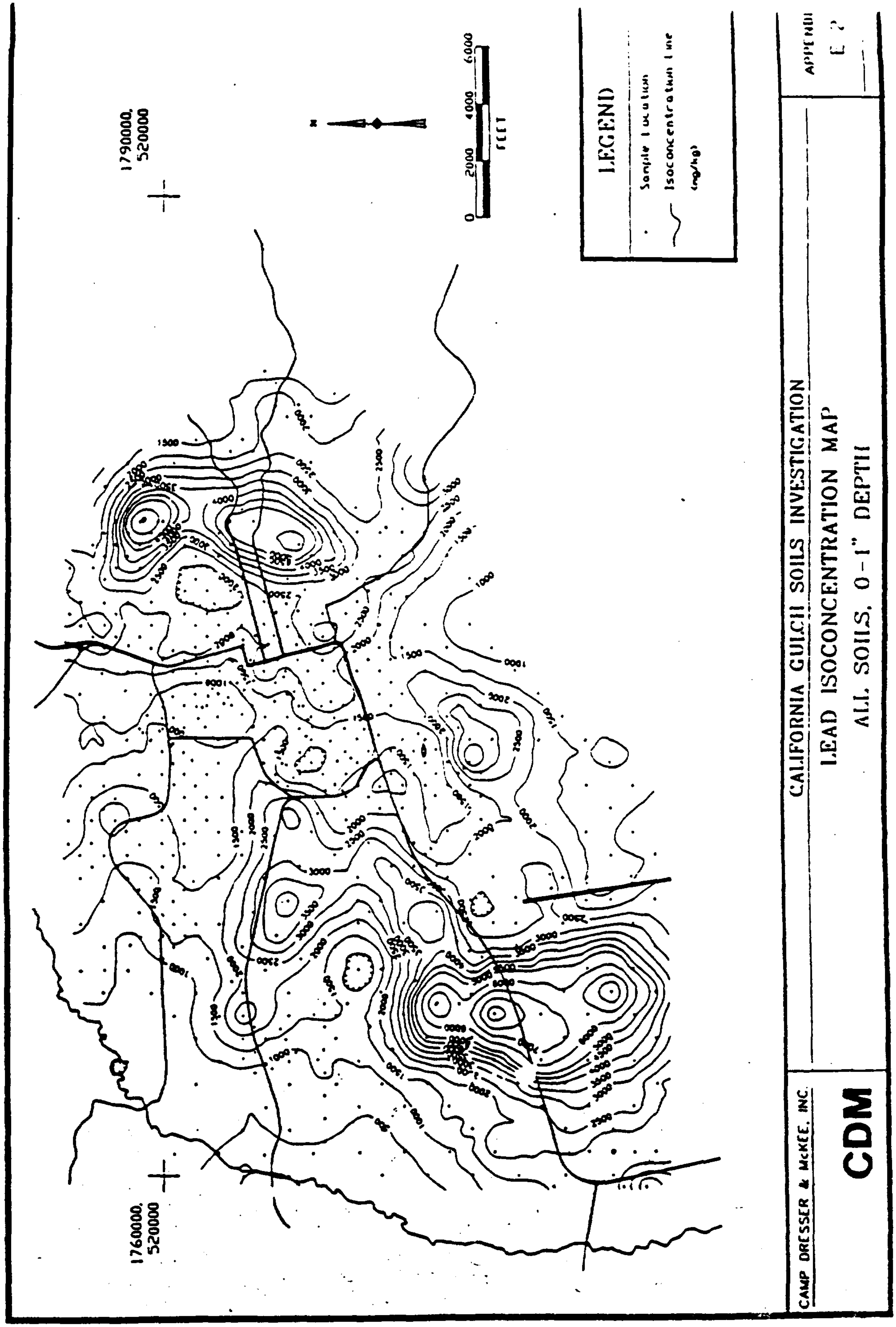


Figure 2: Lead Isoconcentration Map

2) Predicted Blood Lead Distribution in Working Women

Use of a mathematical model to predict the range of blood lead values that could occur in working women, now or in the future, also supports the view that there is a low probability that, at the population level, women would be exposed to sufficient environmental lead in the workplace to exceed EPA's health-based goal. However, the predictions of this model are considered to be uncertain, both because the basic model may be an oversimplification of lead exposure and pharmacokinetics in pregnant women, and because of substantial uncertainty in many of the input parameters. In addition, this population-based approach does not identify the range of risks which might occur at specific workplaces.

3) Calculated Action Levels

Even if there is low risk at the population level, it may still be possible for locations to exist where risks to individuals at those locations could be of concern. Calculations of the concentration of lead in soil that is likely to ensure EPA's blood lead goal is not exceeded indicates that concentrations in the range of 6100 to 7700 ppm are likely to be protective with a reasonable degree of confidence. Review of available data on lead concentrations in soil suggest that there are few current workplaces where the mean concentrations are likely to exceed this range of action levels, although there are some locations zoned for possible future commercial development where this range of action levels might be exceeded. As noted above, there is substantial uncertainty in the use of a mathematical model to calculate action levels.

Weight-of Evidence Evaluation

Although all three of these lines of analysis have significant limitations and uncertainties, all three yield generally consistent results, and all support the conclusion that current workplace exposures to environmental lead are unlikely to be of significant concern to working women. Future workplace exposures might be of concern in areas where soil concentrations substantially exceed the range of plausible action levels for lead.

3.0 ARSENIC EVALUATION

No site-specific data are available on the level of arsenic exposure for citizens of Leadville. In the absence of reliable biomarkers of exposure, the level of exposure and risk to workers must be predicted from measured levels of arsenic in the environment. The following sections describe the estimated range of risks from arsenic which might occur in workers, and the range of soil concentrations that are plausible action levels for individual workplaces.

3.1 PREDICTED ARSENIC RISKS IN LEADVILLE WORKERS

3.1.1 Basic Equations

The basic equations recommended by EPA (1989) to predict the risk from arsenic in soil and dust are as follows:

Noncancer Risk

$$HI = (C_s * cHIF_s * RBA_s + C_d * cHIF_d * RBA_d)/oRfD \quad (4)$$

Cancer Risk

$$Risk = (C_s * lHIF_s * RBA_s + C_d * lHIF_d * RBA_d) * oSF \quad (5)$$

where:

cHIF = chronic human intake factor for soil or dust
= (IR/BW)*(EF/365)

lHIF = lifetime average human intake factor for soil or dust
= (IR/BW)*(EF/365)*(ED/AT)

oRfD = Oral reference dose for arsenic

oSF = Oral slope factor for arsenic

3.1.2 Input Parameters

As was discussed previously, exposure parameters vary widely from person to person and from place to place, so it is expected that there is a wide range of doses and risks that could occur in the population of workers in Leadville. Therefore, a Monte Carlo simulation of variability, similar to that described in Section 2.5 above, was used to estimate this range of risks. The PDFs chosen to represent the variability in each input parameter are described below.

C_s and C_d

Data are available from a number of studies on the distribution of arsenic values in soils in the community of Leadville. These data reveal that average arsenic concentrations vary as a function of location within the community, tending to be highest in the eastern sections of town where most of the historic mining-related activities occurred, and southwest of town near the location of the AV smelter. However, for the purposes of simulating the expected distribution of exposures in workers (now or in the future), the most appropriate data are for the community as a whole. Statistics available from several major studies are summarized below.

Study	Sample Type	N	Mean	STD
Walsh 1988	Depth = 0-6"	599	51	81
WESTON 1991	Depth = 0-6"	121	140	181
Bornschein 1994	Perimeter Bare Area	14 28	61 68	153 53
CDM 1994	Depth = 0-6"	3826	83	191

In all of these studies, the data are observed to be left-skewed in an approximately lognormal distribution. Based on these studies, a representative value for the mean is judged to be about 70 ppm and a representative value for the standard deviation is judged to be about 150 ppm. Thus, variability in C_s was estimated with the following PDF:

$$C_s = \text{LOGNORMAL}(70,150)$$

Only one study (Bornschein 1994) has investigated the distribution of arsenic levels in interior dust samples in Leadville. These data were collected in 241 private residences, but it seems reasonable to assume that levels in commercial establishments are likely to be similar. The observed mean and standard deviation of the dust values were 32 ppm and 23 ppm, respectively. As was the case for soils, the data are observed to be left-skewed in an approximately lognormal distribution. Based on this, the value of C_d was modeled as:

$$C_d = \text{LOGNORMAL}(32,23)$$

IR_s and IR_d

The PDFs selected for evaluating soil and dust intake in the workplace are the same as used in Section 2.5 for lead.

ET, ED, and AT

The PDFs selected to model variability in exposure frequency to soil and dust in the workplace are the same as described in Section 2.5 for lead.

Standard guidance (EPA 1991a) indicates that the RME exposure duration for workers is 25 years. Draft guidance (EPA 1993) suggests that the default for central tendency exposure duration is 5 years, although no supporting rational for this value is provided. Assuming that the minimum duration of workplace exposure to environmental arsenic that is of potential toxicological concern is two years, variability in exposure duration was modeled as:

ED = TRIANGULAR(2,5,25)

Averaging time for cancer risks was 70 years (treated as a constant), and averaging time for noncancer was equal to the exposure duration (EPA 1991a).

<u>Body Weight (BW)</u>

Data on the distribution of body weights in males and females has been summarized and analyzed by Brainard and Burmaster (1992). The data are well fit by lognormal distributions, with the following parameters:

Population	Mean of ln(BW) (lbs)	STD of ln(BW) (lbs)
Males	5.14	0.17
Females	4.95	0.21

These PDFs were converted to units of kg (1 lb = 0.454 kg), and the two separate PDFs were combined into one by sampling from each with a relative frequency of 0.5, and fitting the resulting data to a lognormal distribution. The resulting PDF has a GM of 70 kg and a GSD of 1.24. Based on this, the PDF for BW is as follows:

BW = LOGNORMAL2(70,1.24)

<u>RBA</u>

EPA Region VIII guidance recommends a default relative bioavailability factor for arsenic in soil of 0.8 (EPA 1993).

There have not yet been any studies of arsenic absorption from soils from the California Gulch site, but there have been two studies of arsenic absorption from soils collected in Anaconda, Montana (Johnson et al. 1991, Freeman et al. 1994). These studies are subject to some limitations and uncertainties, but the data suggest that in animals (rabbits and monkeys), arsenic absorption from the soil used in these studies is about 20% of that for soluble sodium arsenate. EPA does not feel it is appropriate to extrapolate data from site to site and from sample to sample without careful assessment of the similarity (or lack thereof) in geochemical characteristics of the soils, but these data do suggest that bioavailability of arsenic may vary from location to location. In the absence of any site-specific data, the possible range of arsenic bioavailability in soils at the California Gulch site were modeled as follows:

RBA = UNIFORM(0.2,0.8)

It should be emphasized that this PDF is based on professional judgement only, and might lead to either an overestimate or an underestimate of the true range of RBA for arsenic in site soils.

oRfD and oSF

The oral reference dose and oral cancer slope factors used are those recommended by the EPA (IRIS 1994):

oRfD = 3E-04 mg/kg-d
oSF = 1.75E+00 $(mg/kg\text{-}d)^{-1}$

Although it is likely that there is variability in the susceptibility to arsenic between individuals, these terms were modeled as constants. Uncertainties and controversies regarding these toxicity values are discussed in Part B of this risk assessment.

Summary of Variability PDFs

Table 3 lists the PDFs selected to evaluate the range of arsenic risks that could be experienced by workers in Leadville.

3.1.3 Results

Monte Carlo simulations were performed (5000 iterations per simulation) using the PDFs above to describe the variability in noncancer and cancer risk levels in workers associated with exposure to arsenic in soil or dust at the workplace. The results are summarized below.

Variability Parameter	Risk Estimate	
	Hazard Index	Cancer Risk
Median	2E-02	1E-06
Mean	3E-02	2E-06
95th Percentile	8E-02	7E-06

As shown, the predicted population-based distribution of risks from arsenic is below the normal health-based criterion both for noncancer and cancer effects. However, this does not necessarily prove that there are no specific sublocations within the site where arsenic concentrations in soil and dust might be high enough to be of potential concern to workers at those sublocations. The following section evaluates the range of arsenic concentrations which might be of concern to

TABLE 3. SUMMARY OF VARIABILITY DISTRIBUTION FUNCTIONS FOR ESTIMATION OF ARSENIC EXPOSURE IN WORKERS

Model Input	Abbr.	Units	Distribution Shape	Parameters of Distribution
Concentration in soil	C_s	mg/kg	Lognormal	Mean = 70 STD = 150
Concentration in dust	C_d	mg/kg	Lognormal	Mean = 32 STD = 23
Ingestion rate of soil/dust at workplace	IR_{sd}	mg/day	Triangular	Min = 10 Mode = 30 Max = 120
Exposure frequency at work	EF_t	days/yr	Triangular	Min = 200 Mode = 219 Max = 250
Exposure frequency to soil outdoors	EF_s	days/yr	Triangular	Min = 0 Mode = 10 Max = 100
Exposure frequency to dust indoors	EF_d	days/yr	Calculated as EF_{total} - EF_s	--
Exposure duration at workplace	ED	years	Triangular	Min = 2 Mode = 5 Max = 25
Body weight	BW	kg	Lognormal	GM = 70 GSD = 1.24
Averaging time	AT	years	Noncancer: AT = ED Cancer: AT = 70	--
Arsenic relative bioavailability	RBA	--	Uniform	Min = 0.2 Max = 0.8

individuals at a workplace.

3.2 CALCULATION OF WORKPLACE SOIL ACTION LEVEL FOR ARSENIC

3.2.1 Basic Equation

Recall that the basic equations used to predict noncancer and cancer risks in an individual exposed to arsenic in soil and dust are:

Noncancer Risk

$$HI = (C_s{*}cHIF_s{*}RBA_s + C_d{*}cHIF_d{*}RBA_d)/oRfD \quad (4)$$

Cancer Risk

$$Risk = (C_s{*}lHIF_s{*}RBA_s + C_d{*}lHIF_d{*}RBA_d){*}oSF \quad (5)$$

Because these equations contain terms for both soil and dust exposure, they cannot be solved for the soil term (C_s) unless the dust term (C_d) is defined as a dependent variable whose value can be predicted from the value of soil. Assuming that soil comprises some (but not all) of the mass of indoor dust, the concentration of lead in dust can be described using an equation of the following form:

$$C_d = D_0 + Ksd{*}C_s$$

Setting the value of D_0 to zero (for the reasons discussed previously), and substituting this expression into the basic equations above, the equations for calculating the noncancer and cancer action levels for arsenic are as follows:

$$AL_{nc} = HI_{target}{*}oRfD/(cHIF_s{*}RBA_s + K_{sd}{*}cHIF_d) \quad (6)$$

$$AL_c = Risk_{target}/((lHIF_s{*}RBA_s + K_{sd}{*}lHIF_d){*}oSF) \quad (6)$$

The overall action level for soil is then the more stringent (lower) of these two values:

Typically, the health-based goals for these calculations are that a person at the upper portion of the dose distribution (i.e., the RME individual) should have a Hazard Index which does not exceed 1E+00 and an excess cancer risk which does not exceed 1E-04. Screening level calculations show that for arsenic, based on these health goals, it is cancer risk which yields the more stringent action level. Therefore, only the equation for the cancer-based action level is evaluated below.

3.2.2 Uncertainty PDFs

The object of the action level calculation is to estimate a concentration that will be protective even for a person at the upper end of the exposure distribution. Therefore, several of the inputs into the equation above are intended to be values appropriate for the RME individual. If the true values of these RME parameters were known, then the equation would yield a single numeric value (the action level) that is equal to the soil arsenic concentration that ensures the heath-based goals are met for RME individuals. However, there is substantial uncertainty in the true value for most of these variables. Therefore, each input parameter was described by a PDF which describes uncertainty about the intended value, and these PDFs were used in a Monte Carlo simulation to estimate the plausible range of the action level.

<u>RME IR_s and IR_d</u>

Draft EPA guidance specifies that the RME soil and dust intake by workers should be 100 mg/day. Because this estimate is based on relatively little data, it is considered to be highly uncertain. Based on professional judgement, uncertainty about this parameter was modeled as:

$$\text{RME } IR_{sd} = \text{UNIFORM}(50,200)$$

<u>Exposure Frequency</u>

The same uncertainty PDFs for workplace exposure frequency to soil and dust that were used to evaluate the action level for lead were also used to evaluate uncertainty in the action level for arsenic.

<u>RME Exposure Duration</u>

EPA guidance specifies that the RME exposure duration for workers should be 25 years, but does not provide any information on the confidence in that value. Based on professional judgement, uncertainty about this parameter was modeled as follows:

$$\text{RME ED} = \text{UNIFORM}(20,30)$$

<u>Averaging Time</u>

Averaging time was assumed to be 70 years, and this was treated as a constant rather than an uncertain variable. This is because application of the cancer slope factor for arsenic is based on the assumption of a 70-year lifetime.

<u>Mean Body Weight</u>

Data on adult body weights are derived from measurements in a very large number of people, so there is very little uncertainty in the true mean value. Because of this, the value for body weight was simply treated as a constant (70 kg).

RME Relative Bioavailability

There are presently no measurements of arsenic relative bioavailability in site-specific soils or dusts, so it is difficult to evaluate the uncertainty around the default RME value of 0.8. Based on professional judgement, the following PDF was used:

RME RBA = UNIFORM(0.7,0.9)

Soil/Dust Relationship (K_{sd})

Data on the relationship between arsenic concentration levels in dust and soil (C_s, C_d) are available from the environmental data set collected by the University of Cincinnati in 1991. Employing the same analysis approach as described in Part B and in Section 2.6.3 (above), the values estimated for D_0 and K_{sd} are as follows:

Parameter	Soil Type	
	Perimeter	Bare Area
Number of paired samples	14	28
Mean of dust ($\bar{D}$)	51	33
Mean of soil ($\bar{S}$)	61	68
Estimated D_0[a]	29	18
Calculated K_{sd}[b]	0.36	0.22

[a] Mean of dust samples where soil arsenic is low (< 10 ppm)
[b] Calculated as ($\bar{D}$ - D_0)/($\bar{S}$)

Because these calculations are based on a rather small data set, the results are considered to be rather uncertain. Therefore, the uncertainty around the mean value of Ksd was modeled as:

K_{sd} = UNIFORM(0.2,0.6)

As noted above, the value of D_0 is set at zero for the purposes of estimating an action level.

Summary of Uncertainty PDFs

Table 4 summarizes the PDFs selected to describe the uncertainty around the inputs needed to calculate an action level for workers exposed to arsenic in soil and dust.

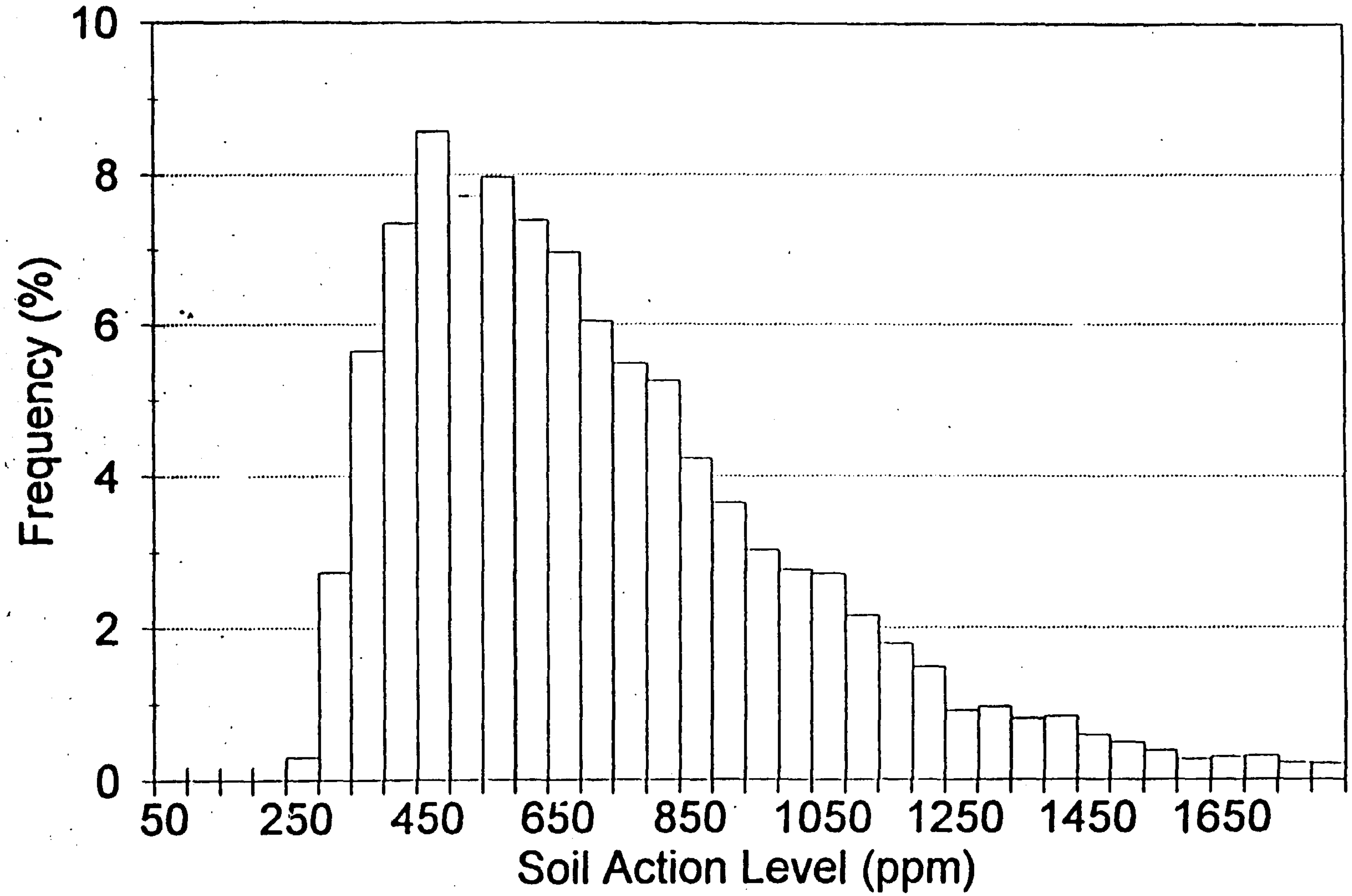
3.2.3 Results

The results of a Monte Carlo simulation of the uncertainty around the action level are shown in Figure 3. As seen, the plausible range of action levels could conceivably range from as low as

TABLE 4. SUMMARY OF UNCERTAINTY DISTRIBUTION FUNCTIONS FOR ESTIMATION OF ARSENIC SOIL ACTION LEVEL

Model Input	Abbr.	Units	Distribution Shape	Parameters of Distribution
RME ingestion rate of soil/dust	IR_{sd}	mg/day	Uniform	Min = 50 Max = 150
RME exposure frequency at work	EF_t	days/yr	Uniform	Min = 240 Max = 260
Exposure frequency to soil outdoors	EF_s	days/yr	Triangular	Min = 5 Mode = 10 Max = 20
Exposure frequency to dust indoors	EF_d	days/yr	Calculated as: $EF_{total} - EF_s$	--
RME exposure duration at workplace	ED	years	Uniform	Min = 20 Max = 30
Body weight	BW	kg	Constant	70
Averaging time	AT	years	Constant	70
Mass fraction of soil in dust	Ksd	--	Uniform	Min = 0.2 Max = 0.6
RME relative bioavailability	RBA	--	Uniform	Min = 0.7 Max = 0.9

Figure 3 Uncertainty in Soil Action Level for Arsenic



330 ppm (the 5th percentile) to as high as 1300 ppm (the 95th percentile). Central tendency values include 610 ppm (the geometric mean) and 690 ppm (the arithmetic mean).

3.2.4 Comparison with Site Concentrations

Data on arsenic levels measured in surficial soil (0-1 inch) in and around Leadville are shown in Figure 4 (CDM 1994). Inspection of this map reveals that average arsenic levels are not expected to exceed about 50 ppm in the main business section of Leadville, and that expected mean levels do not appear to exceed the soil action level for workers anywhere at the site except possibly for the area near the former AV Smelter located southwest of town.

As before, it is important to understand that it is average arsenic level over an area which should be compared to the soil action level. That is, occasional measurements or small "hot-spots" of concentrations above the action level do not necessarily constitute evidence that an area is unsafe.

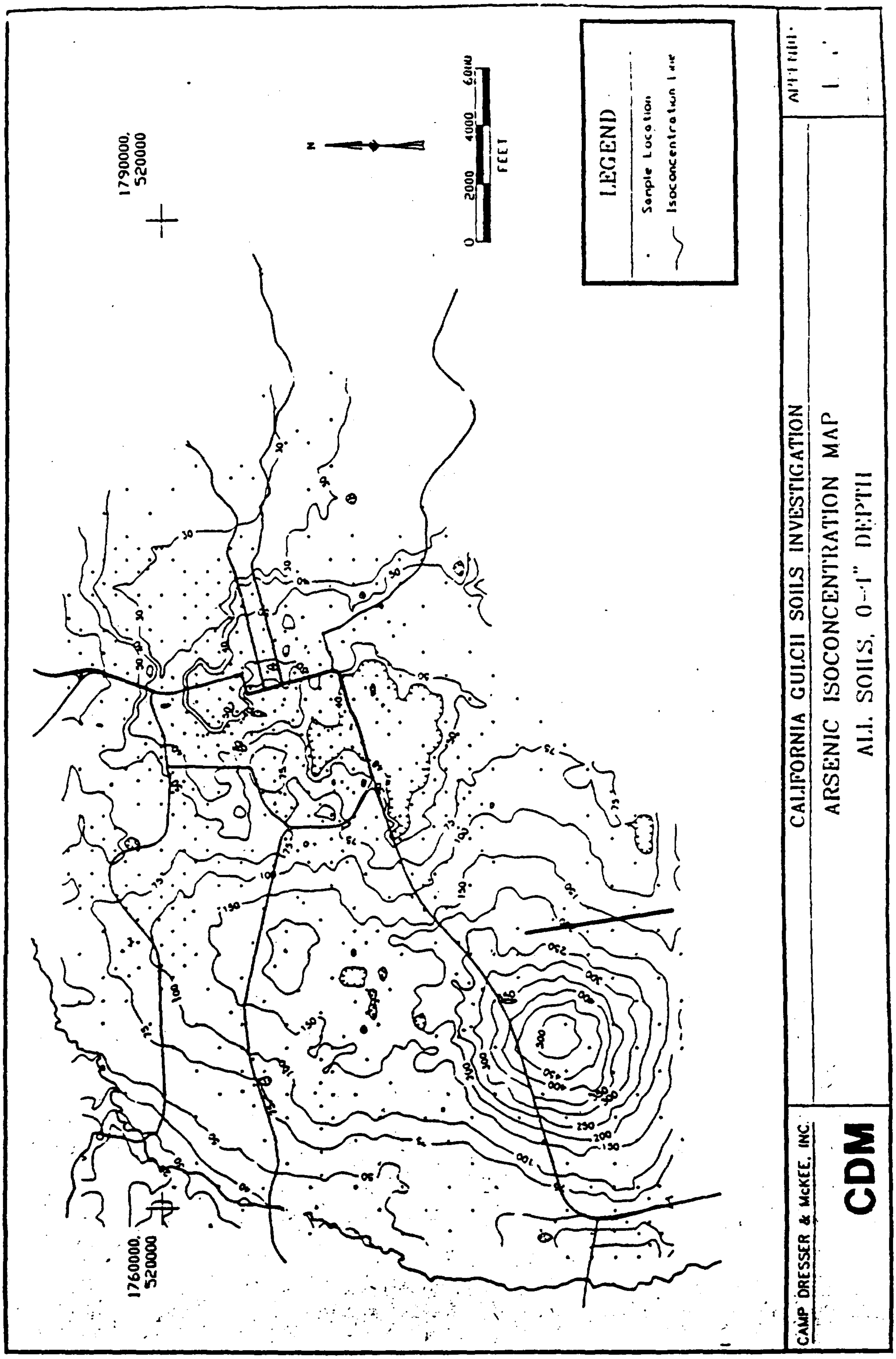


Figure 4: Arsenic Isoconcentration Map

4.0 DISCUSSION AND CONCLUSIONS

There is inherent uncertainty in the approaches used above to evaluate risks to workers from lead and arsenic in soil and to derive workplace soil action levels for these contaminants. Specifically:

- There is uncertainty in the direct measurements of blood lead in women, since this approach may not detect specific locations where risks are high, and may not describe risks which could occur in the future

- There is uncertainty in the basic mathematical models used to calculate risk, both for lead and for arsenic, since these models are likely to be over-simplifications of the true biological processes occurring

- There is uncertainty in the inputs used to calculate risk and action levels for lead and arsenic, especially in key human exposure parameters such as soil and dust ingestion rates and gastrointestinal absorption fractions

- There is debate over the appropriate target blood level in women, and in the cancer slope factor used to estimate cancer risks from arsenic

Despite these uncertainties, the weight of evidence from the analyses detailed above supports the conclusion that there is relatively low probability that current workers are exposed to concentrations of either lead or arsenic which pose substantial risk. In the future, if workplaces were developed in areas where environmental levels significantly exceed the range of plausible action levels, risks to workers at those locations might be of potential concern.

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APPENDIX A

ESTIMATION OF LEAD BKSF

Introduction

Pocock et al. (1983) observed a strong correlation between blood lead level in over 7,300 adult males and the concentration of lead in first draw water. The slope was 0.60 ug/dL per ug/L. This slope can be used to estimate the biokinetic slope factor (BKSF) for lead by dividing by the average absorbed dose of lead per ug/L in first draw water. However, a number of assumptions are required to estimate the average absorbed dose. The basic equation is:

$$AD_w = C_{1st} \cdot IR_{1st} \cdot AF_{1st} + C_f \cdot IR_f \cdot AF_f$$

where:

C = Concentration in first draw water (C_{1st}) or flushed water (C_f)
AF = Absorption fraction from first draw water (AF_{1st}) or flushed water (AF_f)
IR = Ingestion rate of first draw water (IR_{1st}) or flushed water (IR_f)

Assumptions regarding each of these parameters are discussed below.

Water Ingestion

There are no data from the Pocock study of how much water of either type (first draw or flushed) was ingested, or on the reduction in concentration in flushed water compared to first draw. However, based on observations at other sites (White 1995), it is probably reasonable to expect that no more than 30% of the total water ingested is first draw. Assuming a total water intake of 1.4 L/day, this corresponds to intakes of 0.42 L/day (first draw) and 0.98 L/day (flushed).

Concentration in Flushed Water

Pocock et a' did not report the concentration of water after flushing the pipes, but observations at other sites suggest that the concentration of lead in flushed water is usually about 25% of that in first draw water (White, 1995).

Absorption Fraction

As discussed in the main text of this assessment, the absorption fraction for lead in adults ranges from about 10% (if the lead is ingested along with food) to about 35% (if the lead is ingested after a fast) (Rabinowitz et al. 1980). No information is available on whether the men in the Pocock study ingested water with or without food, but it seems plausible to suppose that first draw water would be ingested early in the day, perhaps before breakfast, so an absorption fraction of 0.3 was assumed for this water. For flushed water ingested during the remainder of the day, it seems reasonable to assume that this will be ingested along with food, or at least within several hours of eating, so an absorption fraction of 10% was assumed for this water.

Summary and Results

The input parameters used to estimate BKSF from the data of Pocock are summarized below.

Parameter	1st Draw	Flushed
$C/C_{1st\ draw}$	1.00	0.25
IR (L/day)	(0.3)(1.4)=0.42	(0.7)(1.4)=0.98
AF	0.3	0.1

Based on this, the daily absorbed dose is 0.15 ug/day per ug/L in first draw water, and the corresponding BKSF is 0.40 ug/dL per ug/day absorbed. On this basis, Region VIII feels that the Pocock data are consistent with a BKSF of 0.4 ug/dL per ug/day absorbed.

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APPENDIX B. SENSITIVITY ANALYSIS OF BOWERS MODEL

As discussed in Section 2.6, the basic equation used by EPA for calculating soil lead levels that will be protective for adults is:

$$C_s = \frac{(PbB_{GM}target - PbB_0)}{BKSF\cdot(IR_s \cdot EF_s \cdot AF_0 \cdot RBA + K_{sd} \cdot IR_d \cdot EF_d \cdot AF_0 \cdot RBA)}$$

Table B-1 lists a plausible range of input values for each parameter, along with the "best estimate" value at Leadville. Table B-2 shows the approximate local derivative (i.e., the rate of change of the PRG per unit rate of change of the variable) when all inputs are near their best estimate values. As shown, the model is most sensitive to those input parameters which enter into the calculation of the target PbB value (fetal 95th percentile PbB, GSD_i, ratio of fetal to maternal blood). The model is approximately linearly dependent on most other parameters, with a lower dependence on baseline blood lead and exposure frequency outdoors.

The rate of change estimates shown in Table 2 may be misleading, however, since not all input parameters are likely to vary by the same magnitude. The attached graphs show how the model output depends on each input parameter as it varies within the range shown in Table 1. In all cases, the model input parameter being tested was varied around the best estimate value shown in Table 1, while all other parameters were held constant at the best estimate values shown in Table 1. Inspection of these graphs reveals the following pattern of dependency of the PRG on each input parameter as it varies within reasonable limits:

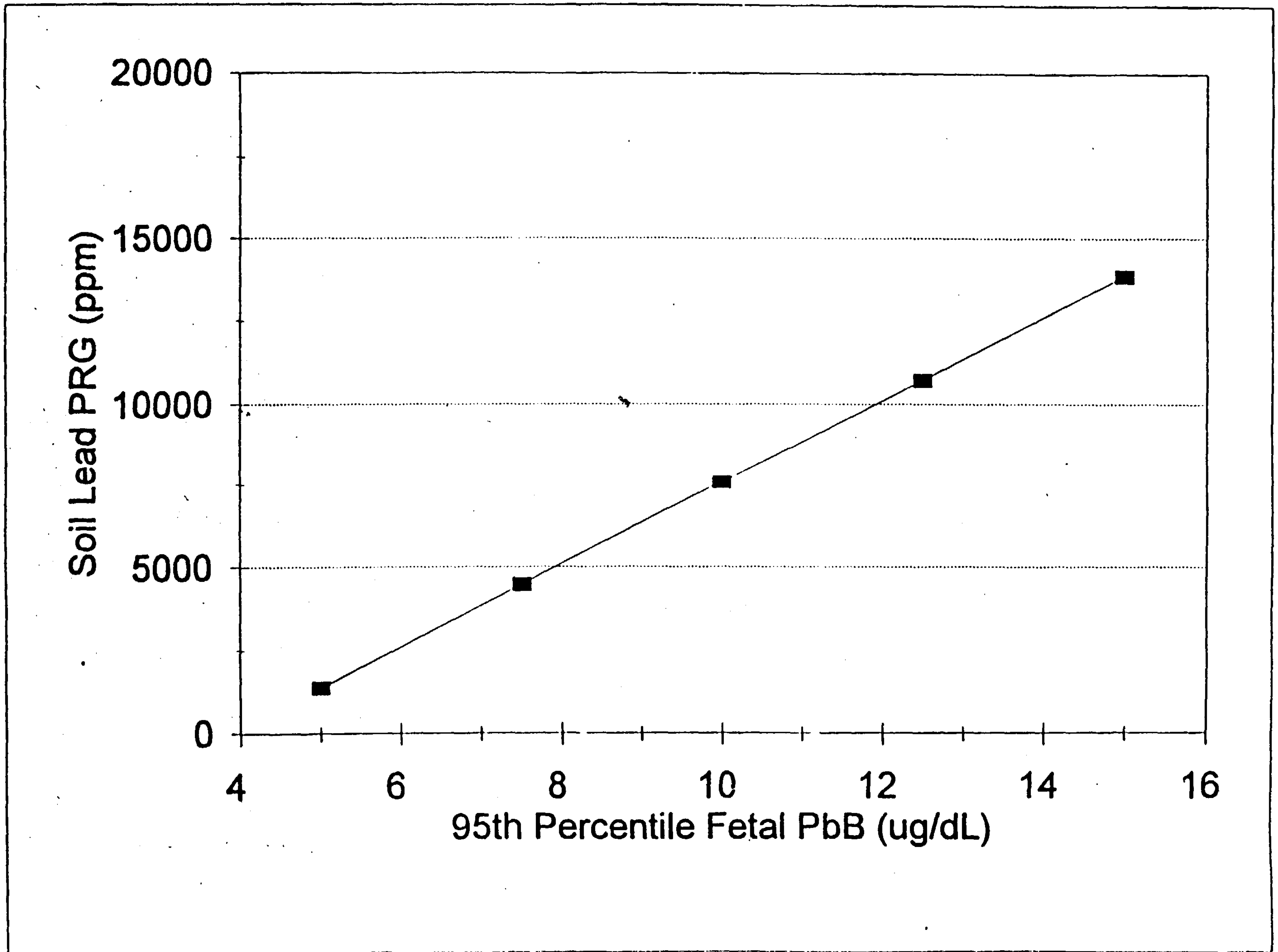
Strength of Dependency	Parameters
Strongly dependent	95th Percentile of Fetal PbB Soil/dust ingestion rate Baseline absorption fraction Mass fraction of soil in dust
Moderately dependent	GSDi RBA
Weakly dependent	Biokinetic slope factor Ratio of fetal to maternal PbB Baseline PbB0 Total exposure frequency Exposure frequency outdoors

TABLE B-1 PLAUSIBLE INPUT PARAMETERS

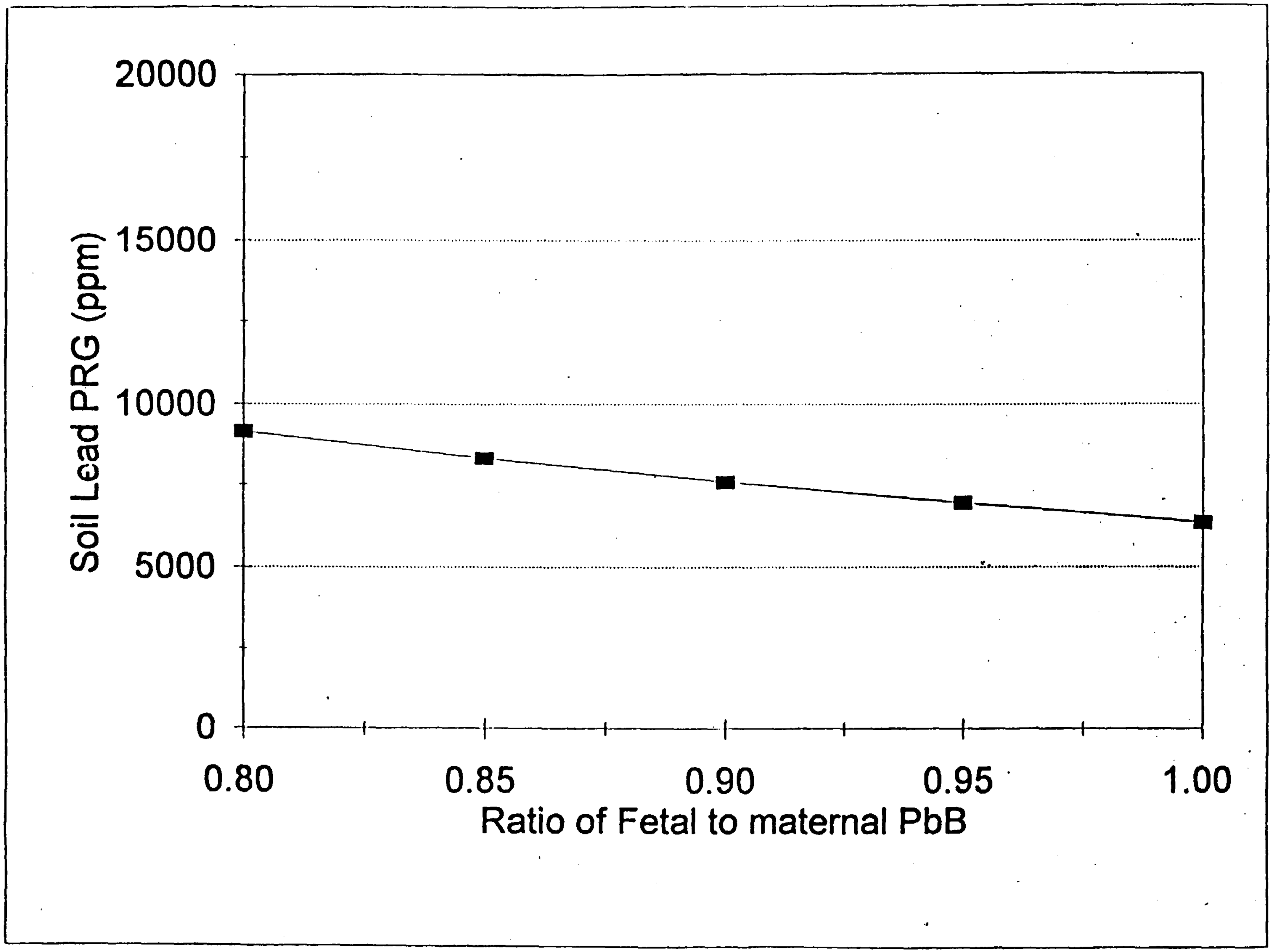
Model Parameter	Plausible Range	Best Estimate
95th Percentile PbB in fetus (ug/dL)	5-15	10
R (Mean ratio of fetal to maternal PbB)	0.8-1.0	0.9
Individual geometric standard deviation (GSD_i)	1.4-1.8	1.6
Baseline blood lead value (PbB0) (ug/dL)	1.6-2.4	2.0
Biokinetic slope factor (BKSF) (ug/dL per ug/day)	0.3-0.5	0.4
Combined soil and dust ingestion rate (IR_{sd}) (mg/day)	10-100	50
Mass fraction of soil in dust (K_{sd})	0.2-0.6	0.25
Total exposure frequency (days/yr)	200-250	220
Exposure frequency outdoors (days/yr)	0-25	10
Oral absorption fraction from food and water	0.1-0.4	0.2
Relative bioavailability in soil or dust	0.4-0.8	0.6

TABLE B-2 RATE OF CHANGE IN ACTION LEVEL PER UNIT CHANGE IN INPUT VARIABLE

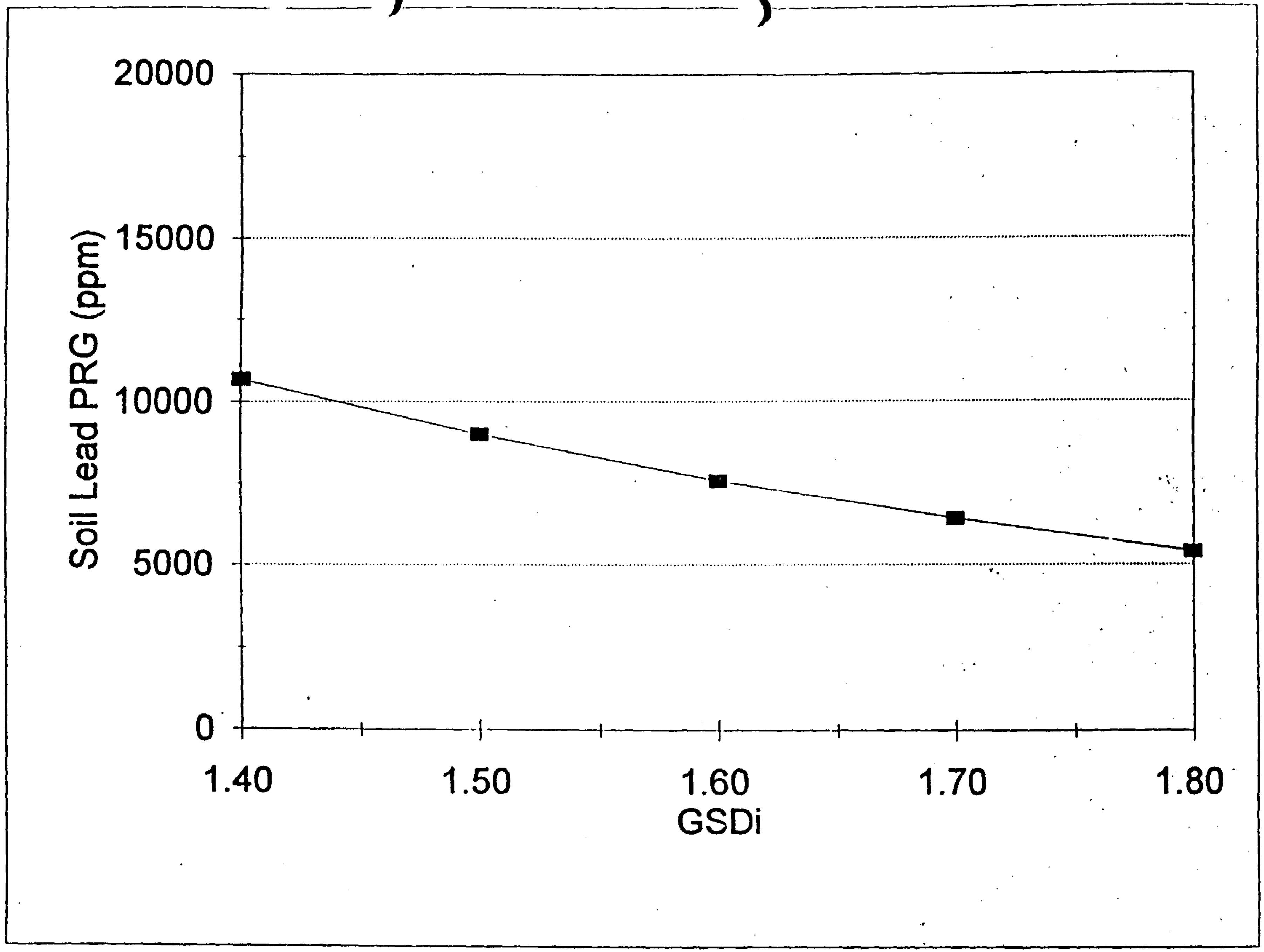
Input Parameter	dY/dX (% per %)
Individual geometric standard deviation (GSD_i)	-2.71
95th Percentile PbB in fetus (ug/dL)	+1.64
R (Mean ratio of fetal to maternal PbB)	-1.64
Combined soil and dust ingestion rate (IR_{sd}) (mg/day)	-1.13
Oral absorption fraction for lead in soil or dust	-1.13
Relative bioavailability	-1.03
Biokinetic slope factor (BKSF) (ug/dL per ug/day)	-1.02
Mass fraction of soil in dust (Ksd)	-0.94
Total exposure frequency	-0.89
Baseline blood lead value (PbB0)	-0.64
Exposure Frequency to outdoor soil (EFs)	-0.17



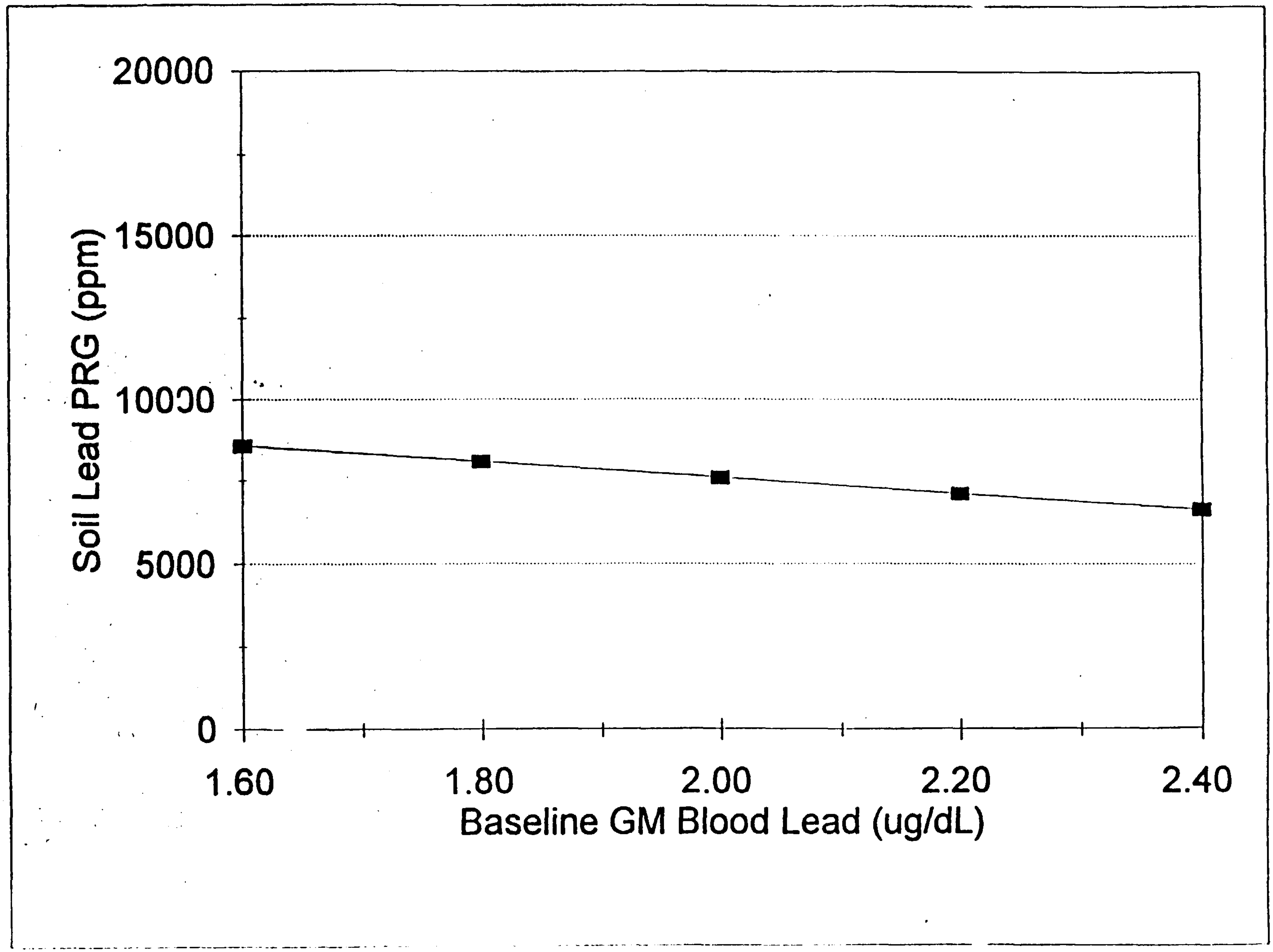
Soil Lead PRG (ppm)
20000
15000
10000
5000
0
4
6
8
10
12
14
16
95th Percentile Fetal PbB (ug/dL)



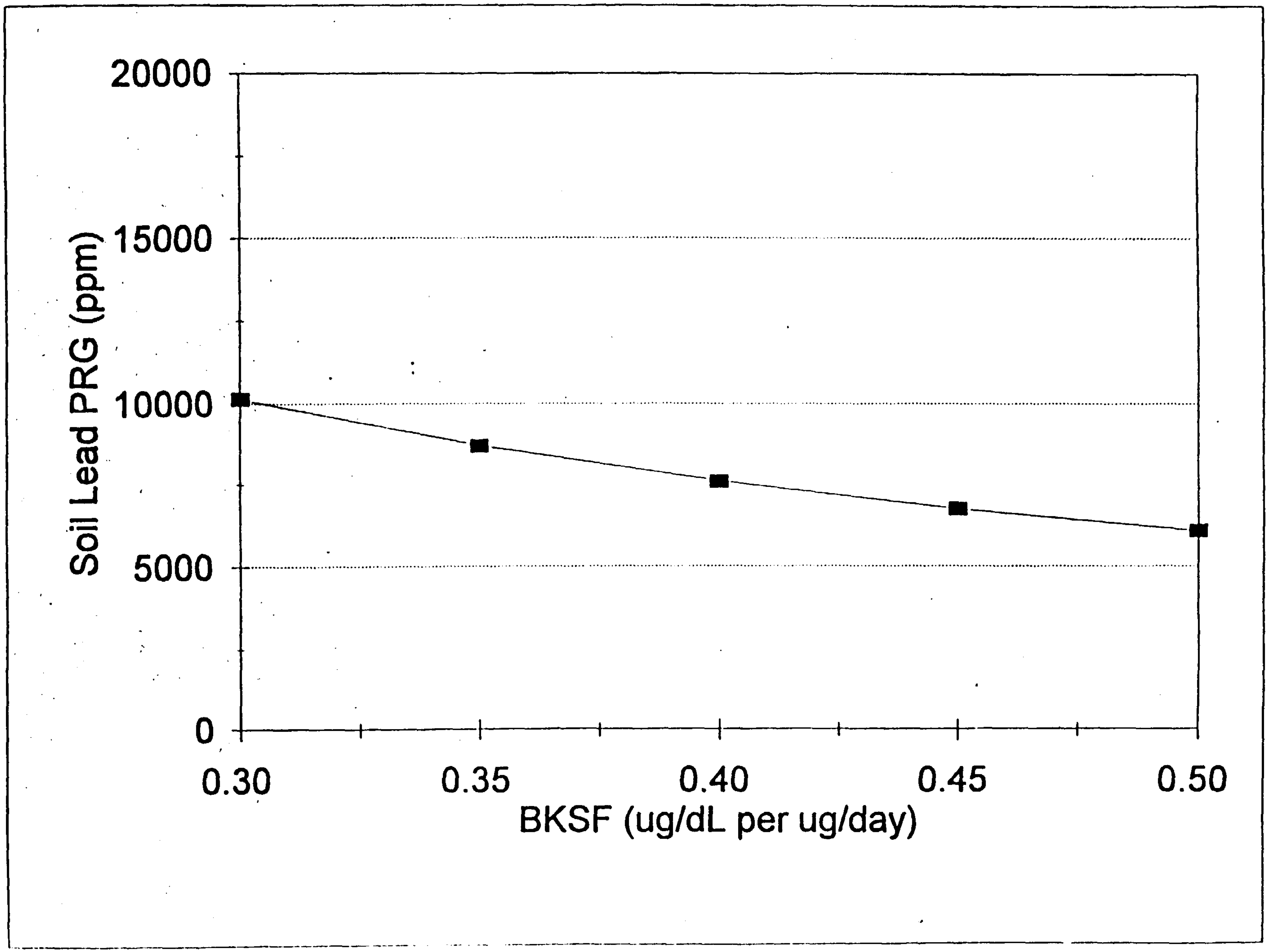
20000
15000
10000
5000
0
Soil Lead PRG (ppm)
0.80
0.85
0.90
0.95
1.00
Ratio of Fetal to maternal PbB



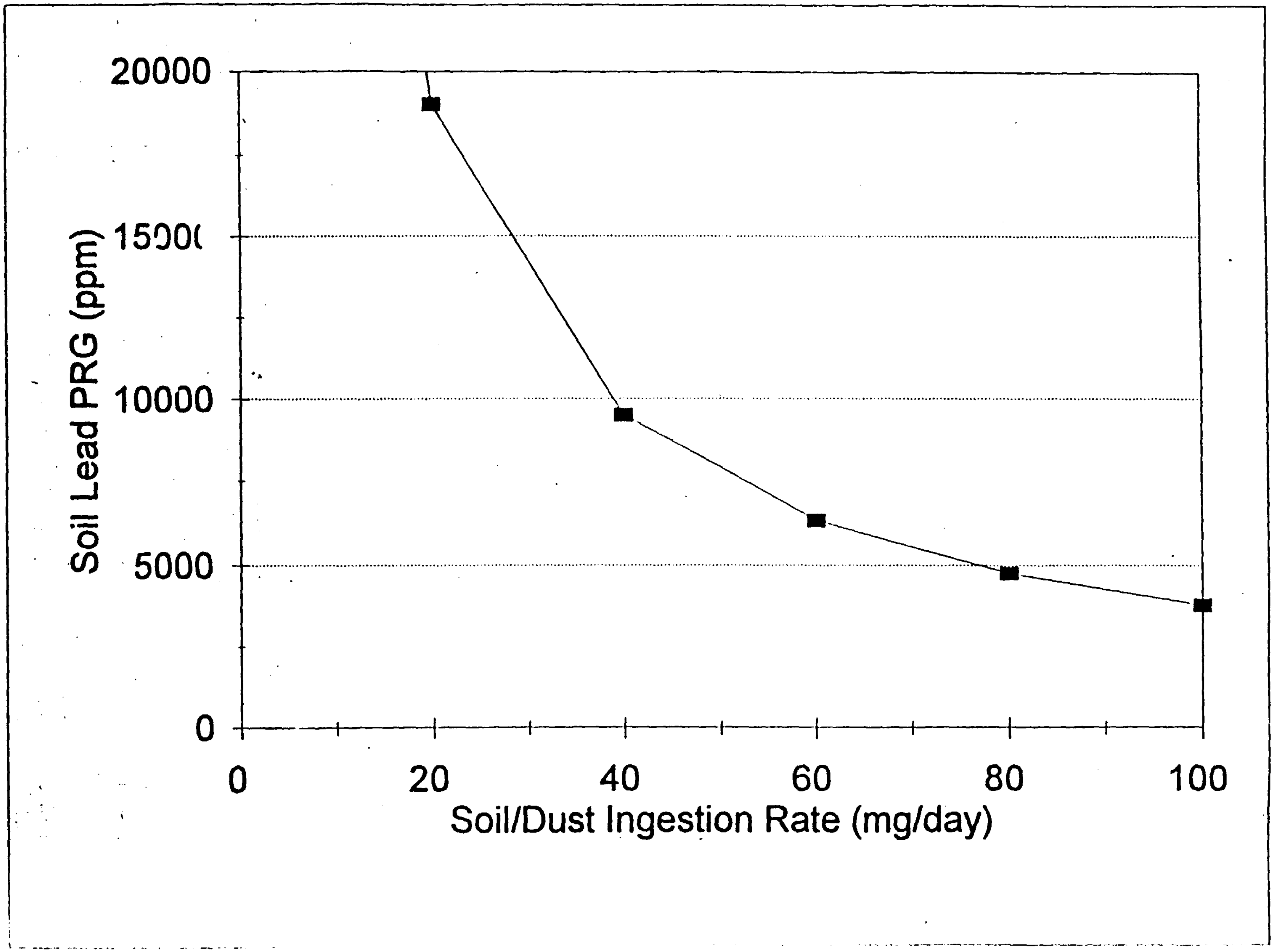
20000
15000
10000
5000
0
Soil Lead PRG (ppm)
1.40
1.50
1.60
1.70
1.80
GSDi



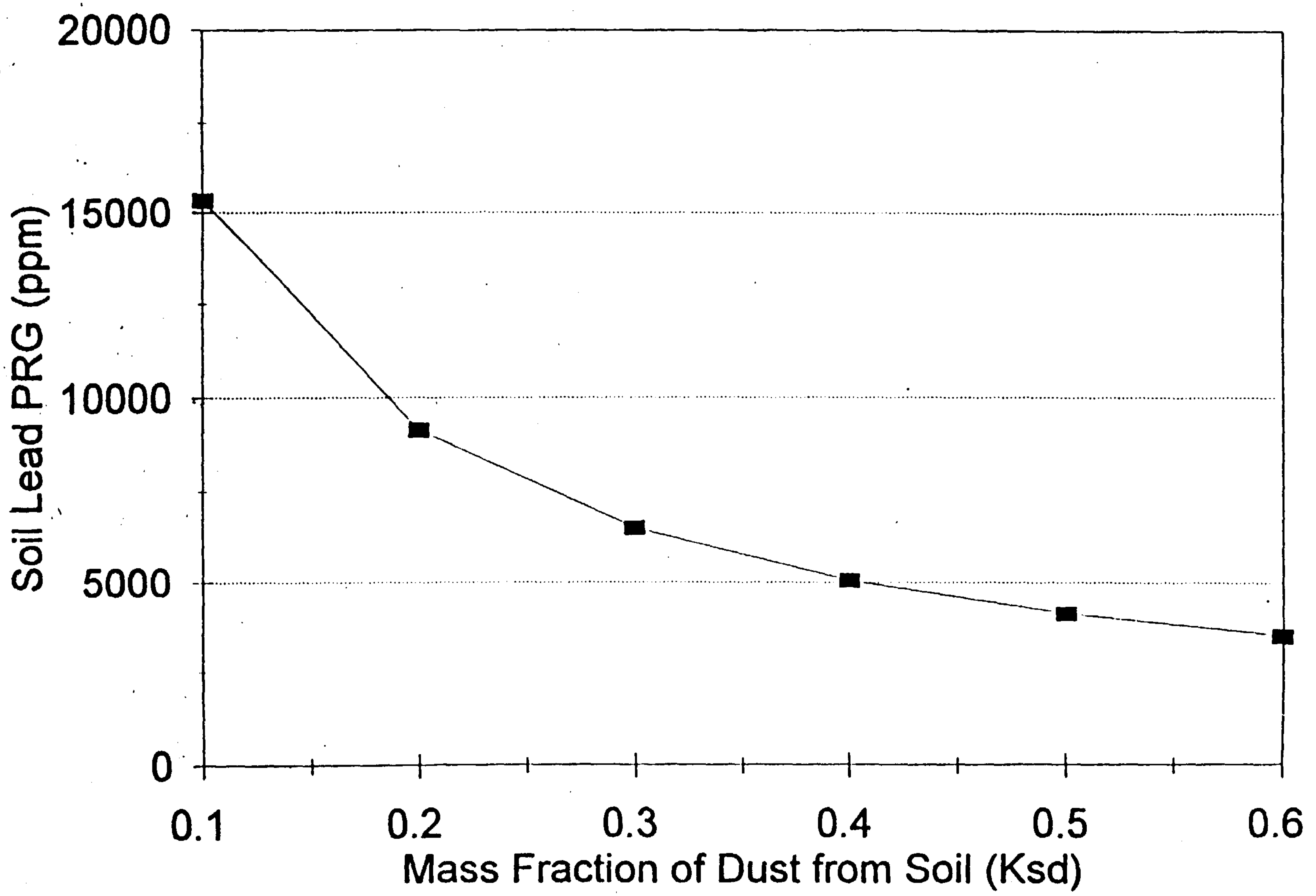
Soil Lead PRG (ppm)
20000
15000
10000
5000
0
1.60
1.80
2.00
2.20
2.40
Baseline GM Blood Lead (ug/dL)



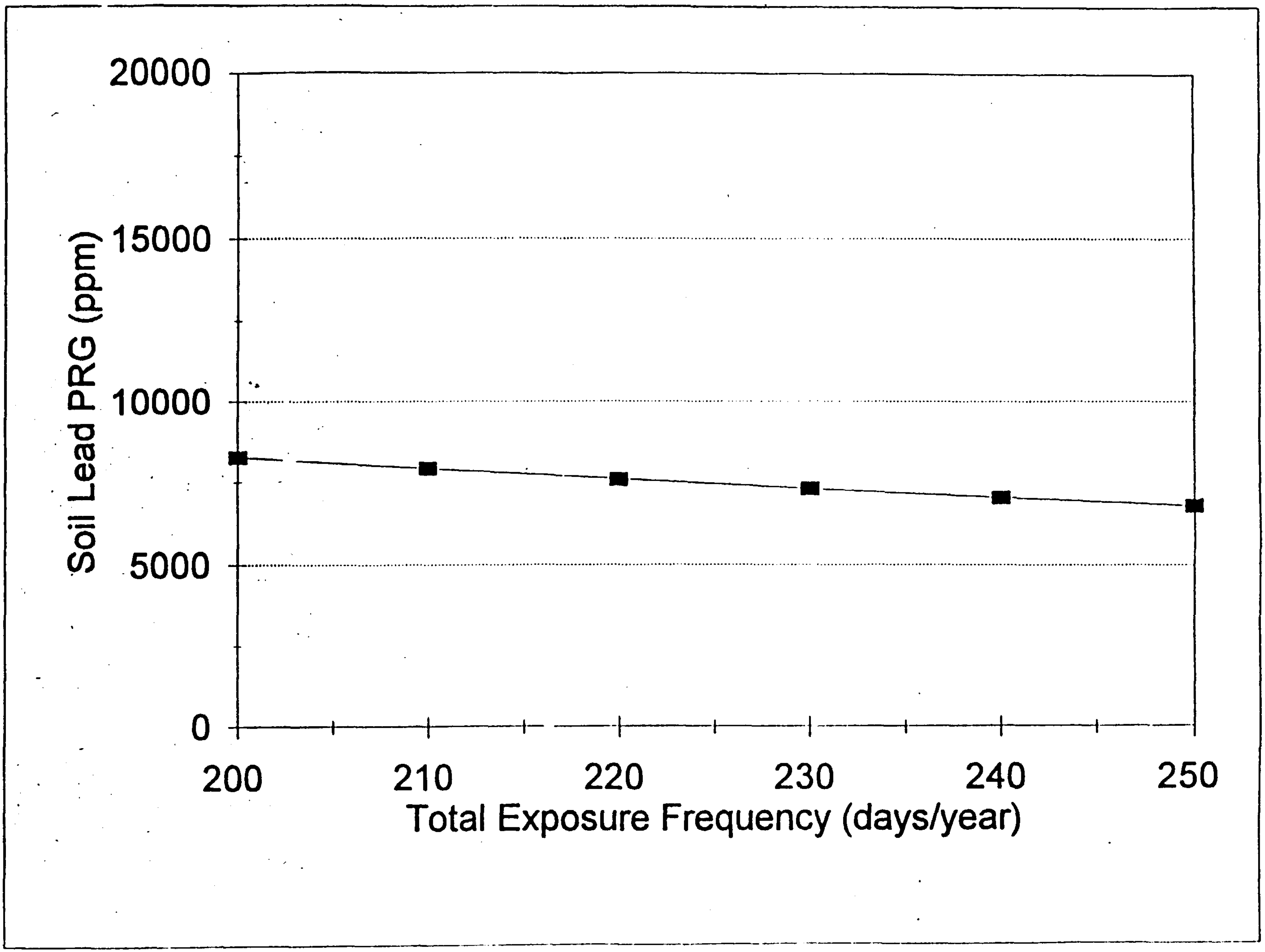
20000
15000
10000
5000
0
Soil Lead PRG (ppm)
0.30
0.35
0.40
0.45
0.50
BKSF (ug/dL per ug/day)



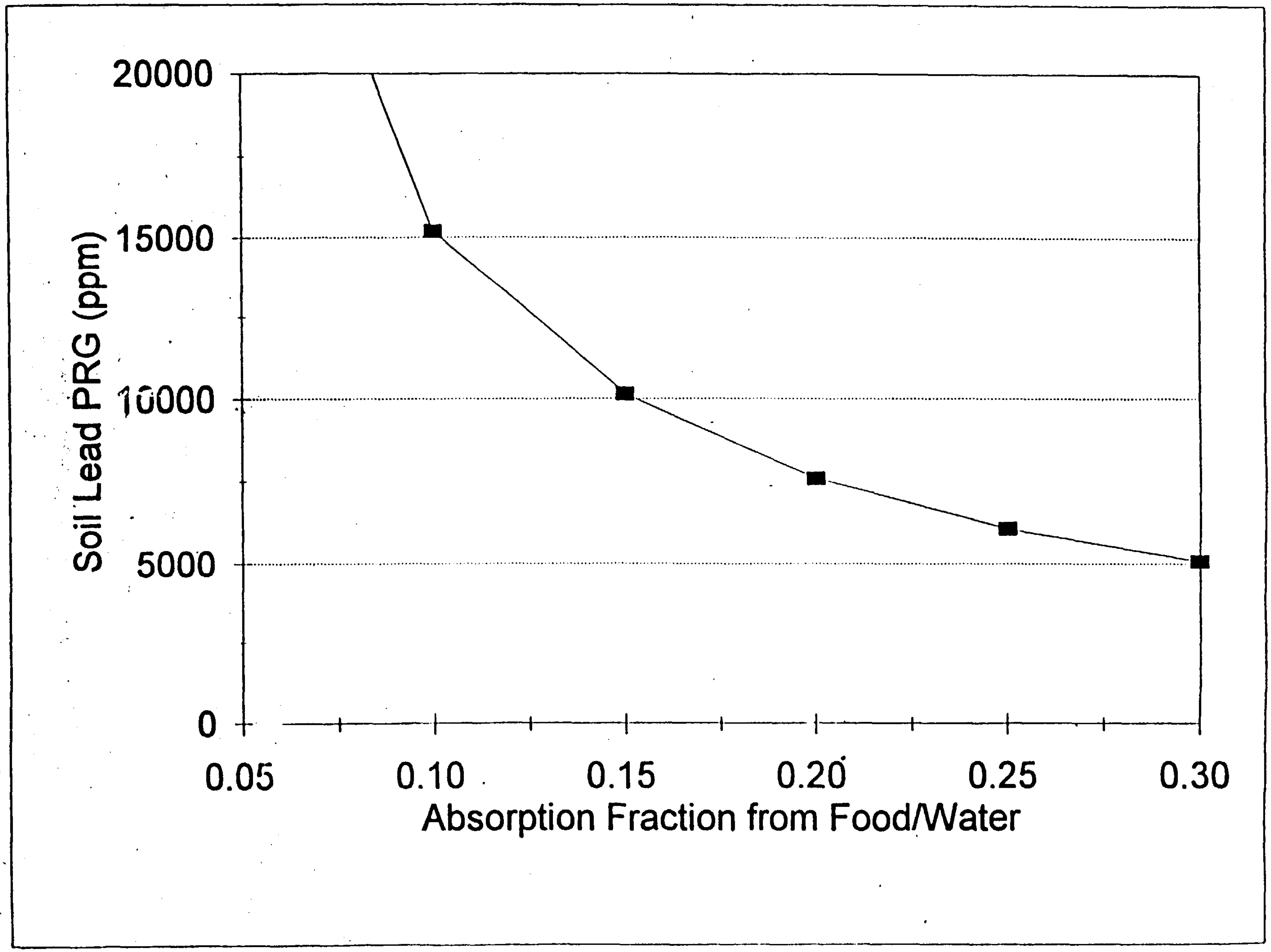
Soil Lead PRG (ppm)
20000
15000
10000
5000
0
0
20
40
60
80
100
Soil/Dust Ingestion Rate (mg/day)



20000
15000
10000
5000
0
Soil Lead PRG (ppm)
0.1
0.2
0.3
0.4
0.5
0.6
Mass Fraction of Dust from Soil (Ksd)



20000
15000
10000
5000
0
Soil Lead PRG (ppm)
200
210
220
230
240
250
Total Exposure Frequency (days/year)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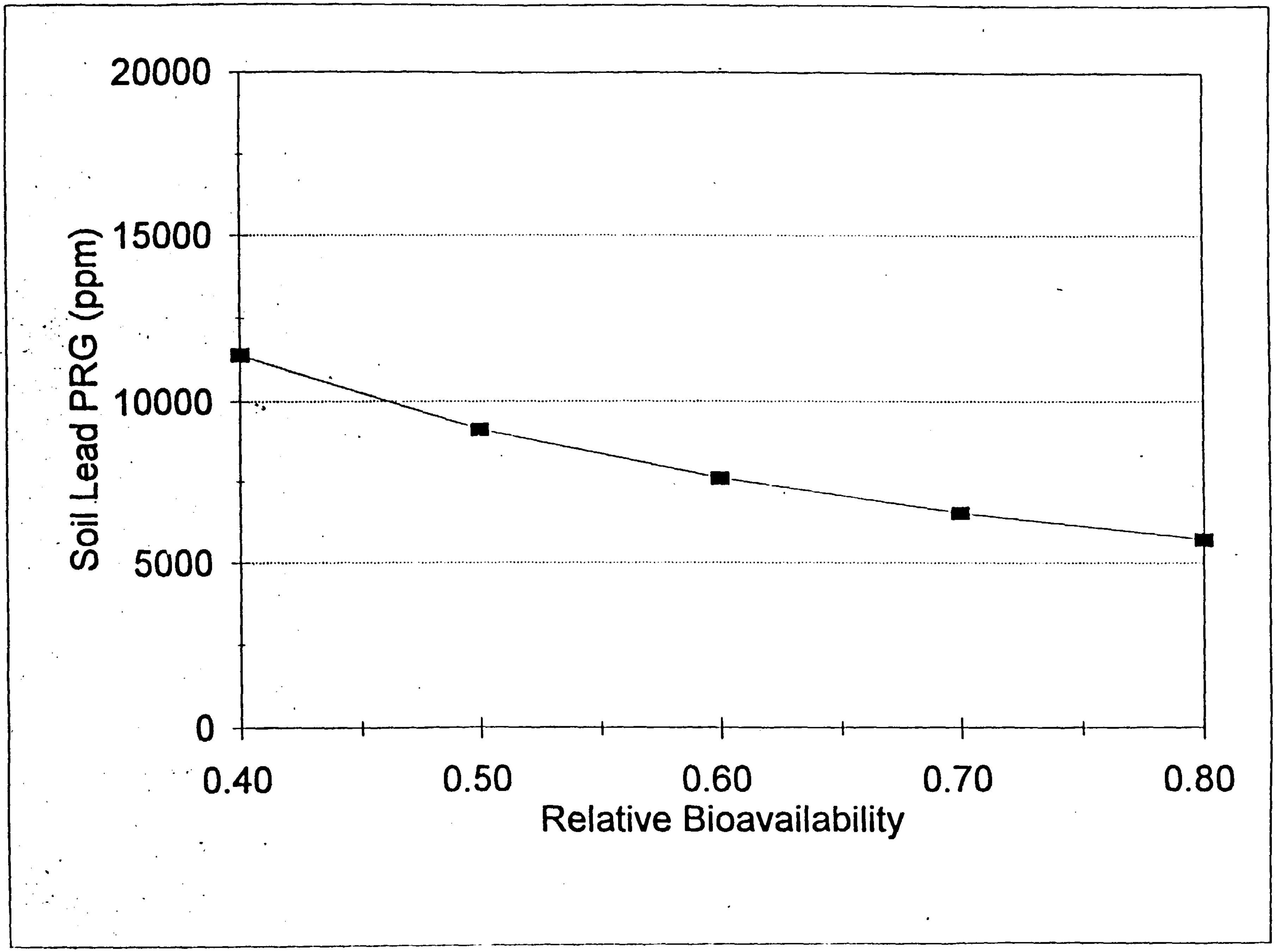
Soil Lead PRG (ppm)
0.05
0.10
0.15
0.20
0.25
0.30
Absorption Fraction from Food/Water


20000
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5000
0
Soil Lead PRG (ppm)
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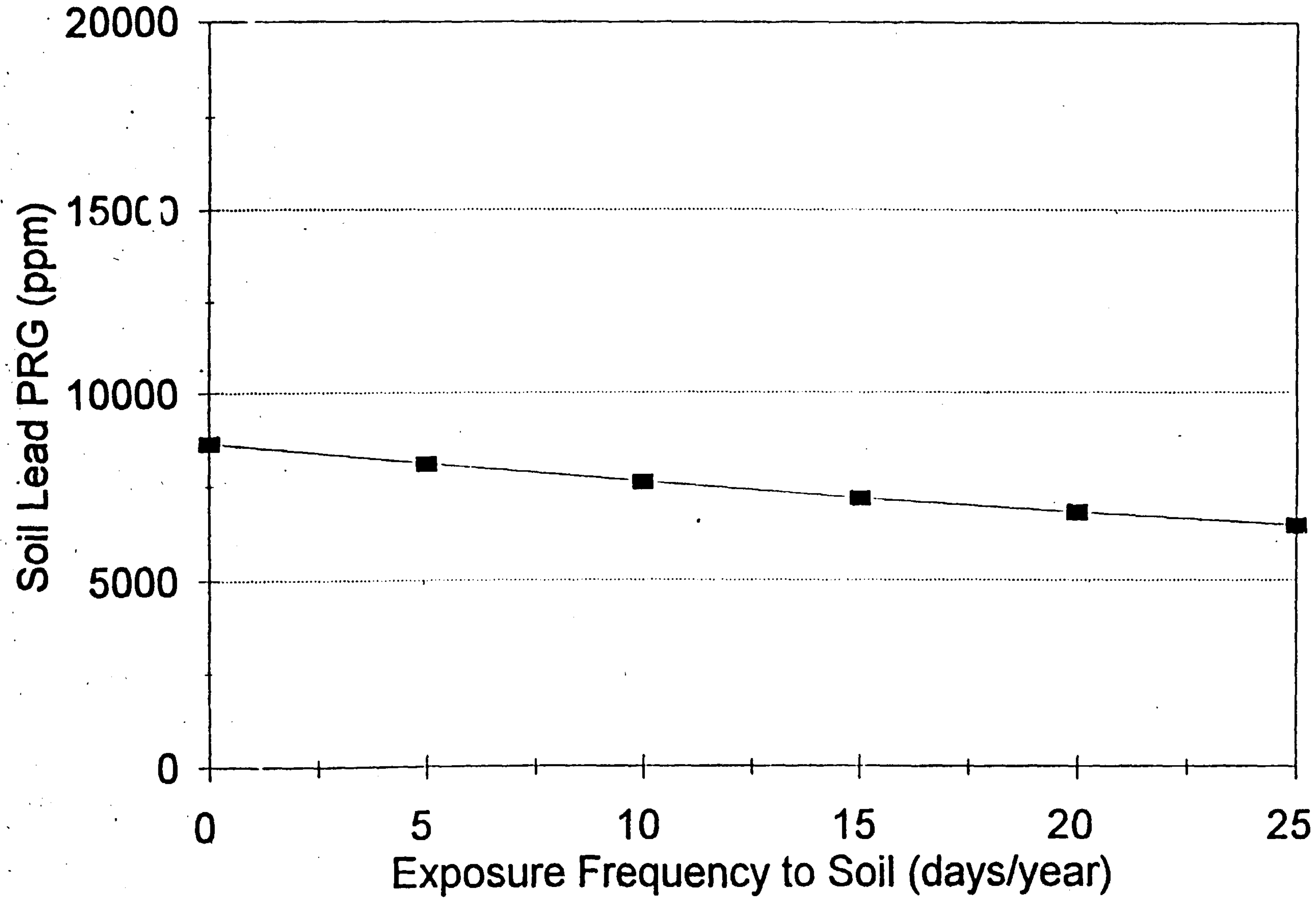
0.60
0.70
0.80
Relative Bioavailability


Soil Lead PRG (ppm)
20000
15000
10000
5000
0
0
5
10
15
20
25
Exposure Frequency to Soil (days/year)